Exhibit 1

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(12) **United States Patent**
Felix et al.

(10) **Patent No.: US 12,161,473 B1**
(45) **Date of Patent: Dec. 10, 2024**

(54) **ELECTROCARDIOGRAPHY PATCH**

(71) Applicant: **Bardy Diagnostics, Inc.**, Bellevue, WA (US)

(72) Inventors: **Jason Felix**, Vashon Island, WA (US); **Jon Mikalson Bishay**, Seattle, WA (US); **Gust H. Bardy**, Carnation, WA (US)

(73) Assignee: **BARDY DIAGNOSTICS, INC.**, Vashon, WA (US)

(*) Notice: Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 0 days.

(21) Appl. No.: **18/800,675**

(22) Filed: **Aug. 12, 2024**

Related U.S. Application Data

(63) Continuation of application No. 18/647,762, filed on Apr. 26, 2024, now Pat. No. 12,089,943, which is a

(Continued)

(51) **Int. Cl.**
A61B 5/335 (2021.01)
A61B 5/00 (2006.01)

(Continued)

(52) **U.S. Cl.**
CPC ***A61B 5/335*** (2021.01); ***A61B 5/0006*** (2013.01); ***A61B 5/0022*** (2013.01);

(Continued)

(58) **Field of Classification Search**
CPC G16H 40/63; G16H 40/67; A61B 2560/0214; A61B 2560/0443; A61B 5/0006; A61B 5/0022; A61B 5/02055; A61B 5/021; A61B 5/03; A61B 5/0816; A61B 5/087; A61B 5/1118; A61B 5/14532; A61B 5/14542; A61B 5/14551; A61B 5/259; A61B 5/282; A61B 5/335;

(Continued)

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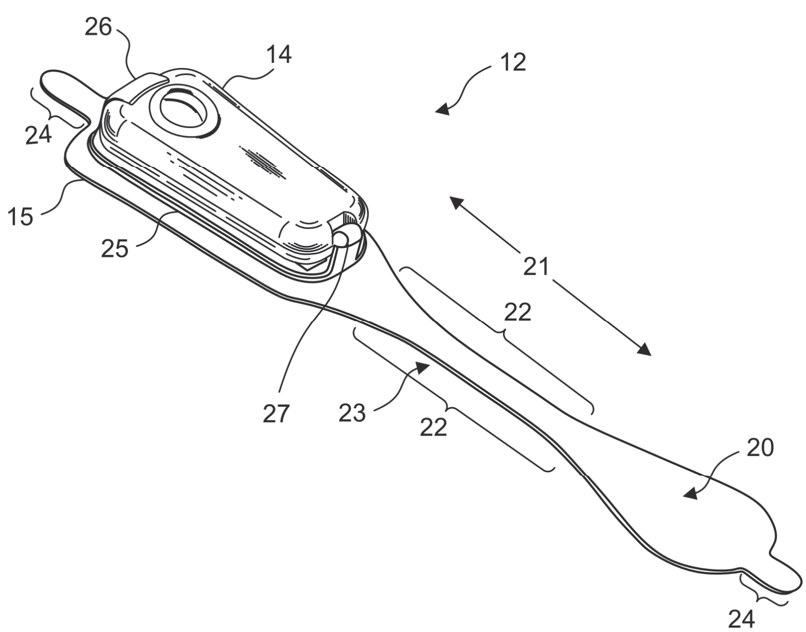
Primary Examiner — George Manuel
(74) *Attorney, Agent, or Firm* — K&L Gates LLP

(57) **ABSTRACT**

An apparatus is provided. A strip has first and second end sections, and a first face and second face. Two electrocardiographic electrodes are provided on the strip with one of the electrocardiographic electrodes provided on the first face of the first end section of the strip and another of the electrocardiographic electrodes positioned on the first face on the second end section of the strip. A flexible circuit is mounted to the second face of the strip and includes a circuit trace electrically coupled to each of the electrocardiographic electrodes. The apparatus includes a wireless transceiver and a battery.

30 Claims, 8 Drawing Sheets



Related U.S. Application Data

continuation of application No. 18/353,398, filed on Jul. 17, 2023, which is a continuation of application No. 17/946,933, filed on Sep. 16, 2022, now Pat. No. 11,723,575, which is a continuation of application No. 17/367,476, filed on Jul. 5, 2021, now Pat. No. 11,445,967, which is a continuation of application No. 17/119,945, filed on Dec. 11, 2020, now Pat. No. 11,051,743, which is a continuation of application No. 16/241,929, filed on Jan. 7, 2019, now Pat. No. 10,888,239, which is a continuation of application No. 15/818,437, filed on Nov. 20, 2017, now Pat. No. 10,172,534, which is a continuation of application No. 15/256,266, filed on Sep. 2, 2016, now Pat. No. 9,820,665, which is a continuation of application No. 14/082,071, filed on Nov. 15, 2013, now Pat. No. 9,433,367, which is a continuation-in-part of application No. 14/080,717, filed on Nov. 14, 2013, now Pat. No. 9,545,204, and a continuation-in-part of application No. 14/080,725, filed on Nov. 14, 2013, now Pat. No. 9,730,593.

(60) Provisional application No. 61/882,403, filed on Sep. 25, 2013.

(51) **Int. Cl.**

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A61B 5/145	(2006.01)
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A61B 5/282	(2021.01)
G16H 40/67	(2018.01)
A61B 5/021	(2006.01)
A61B 5/03	(2006.01)
A61B 5/08	(2006.01)
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A61B 5/11	(2006.01)
A61B 5/1455	(2006.01)
A61B 5/349	(2021.01)

(52) **U.S. Cl.**

CPC ***A61B 5/02055*** (2013.01); ***A61B 5/14532*** (2013.01); ***A61B 5/14542*** (2013.01); ***A61B 5/259*** (2021.01); ***A61B 5/282*** (2021.01); ***A61B 5/6823*** (2013.01); ***A61B 5/6833*** (2013.01); ***A61B 5/7405*** (2013.01); ***A61B 5/7455*** (2013.01); ***A61B 5/7475*** (2013.01); ***G16H 40/67*** (2018.01); *A61B 5/021* (2013.01); *A61B 5/03* (2013.01); *A61B 5/0816* (2013.01); *A61B 5/087* (2013.01); *A61B 5/1118* (2013.01); *A61B 5/14551* (2013.01); *A61B 5/349* (2021.01); *A61B 2560/0214* (2013.01); *A61B 2560/0443* (2013.01)

(58) **Field of Classification Search**

CPC A61B 5/349; A61B 5/6823; A61B 5/6833; A61B 5/7405; A61B 5/7455; A61B 5/7475

See application file for complete search history.

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Fig. 1.

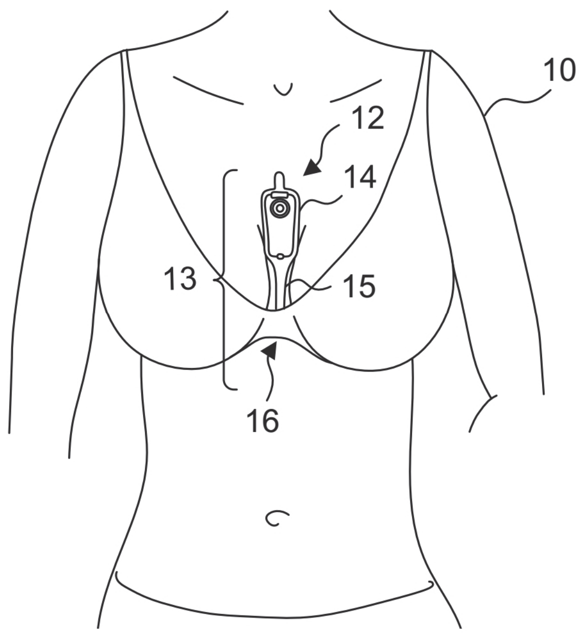


Fig. 2.

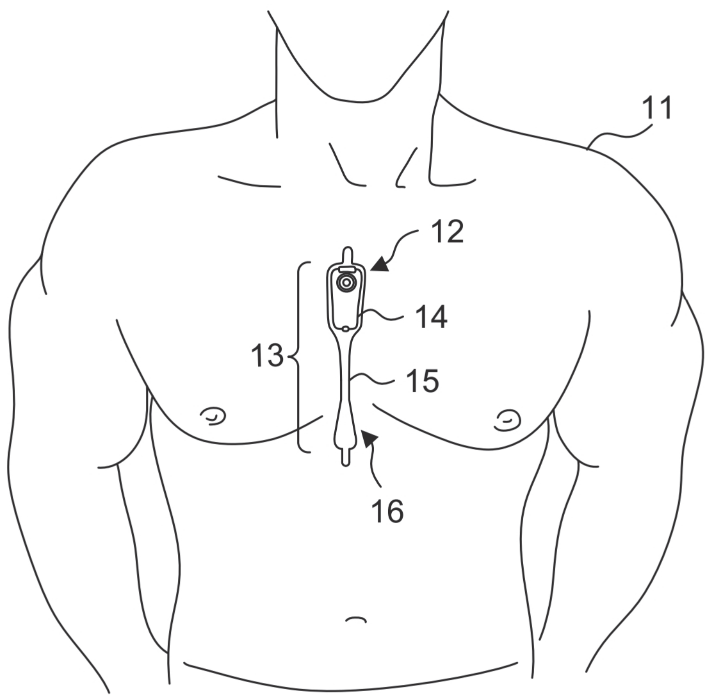
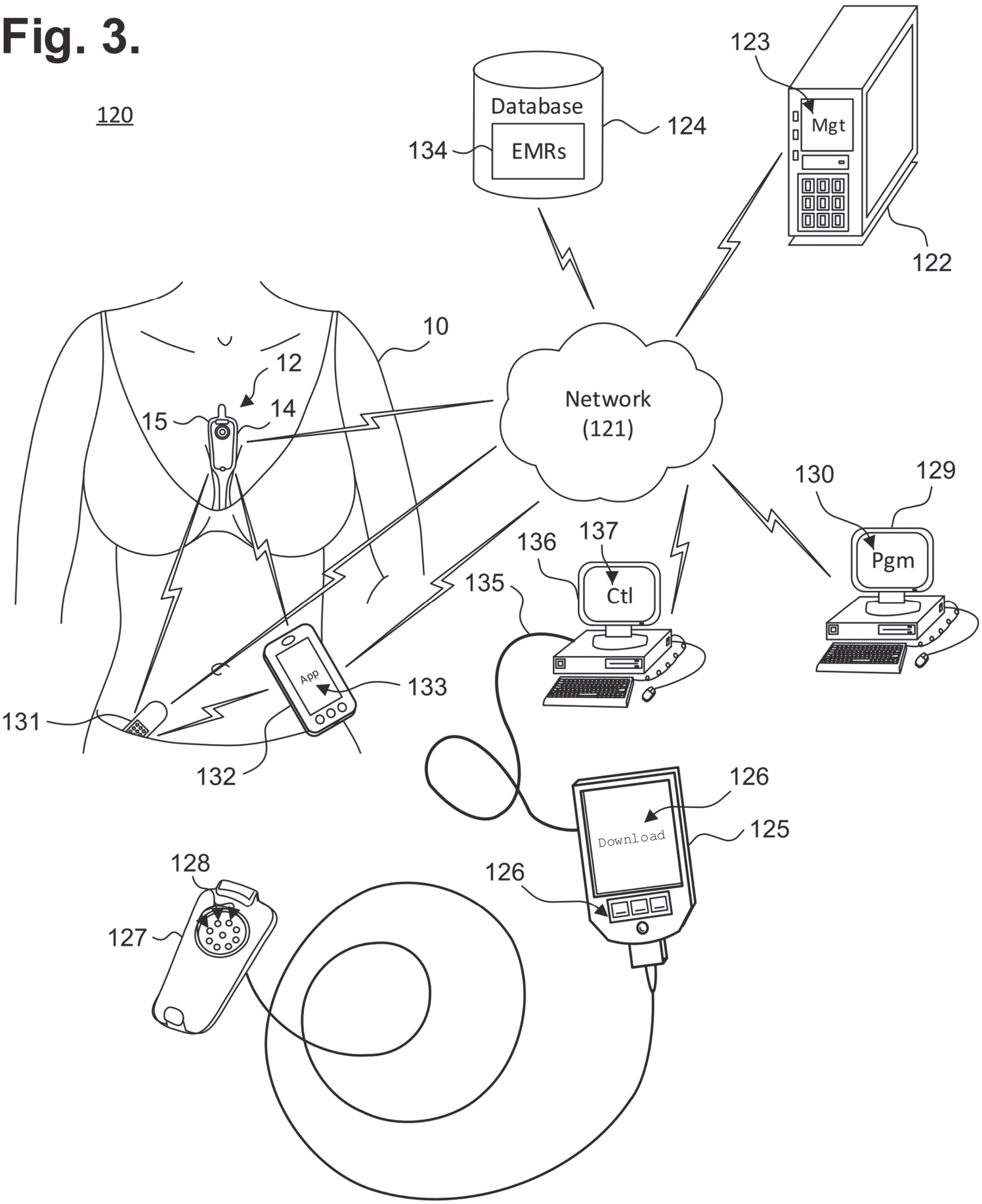
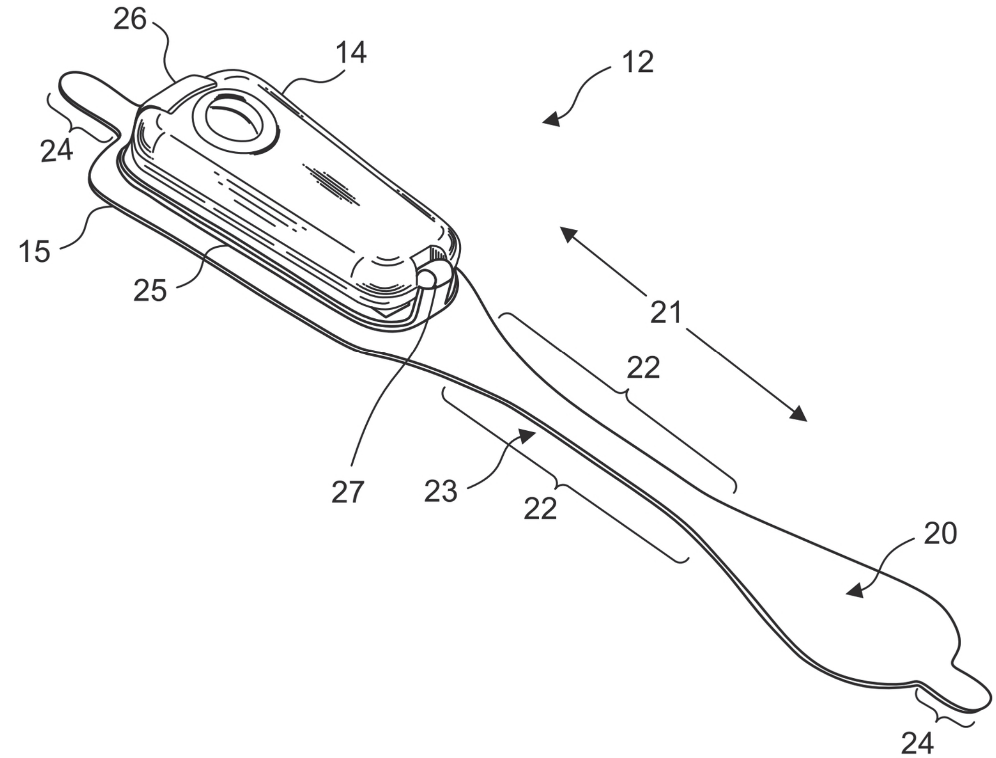


Fig. 3.



120
Database
EMRs
134
124
123
Mgt
122
10
12
15
14
Network
(121)
130
129
Pgm
136
137
Ctl
135
131
App
133
132
126
125
Download
126
128
127

Fig. 4.



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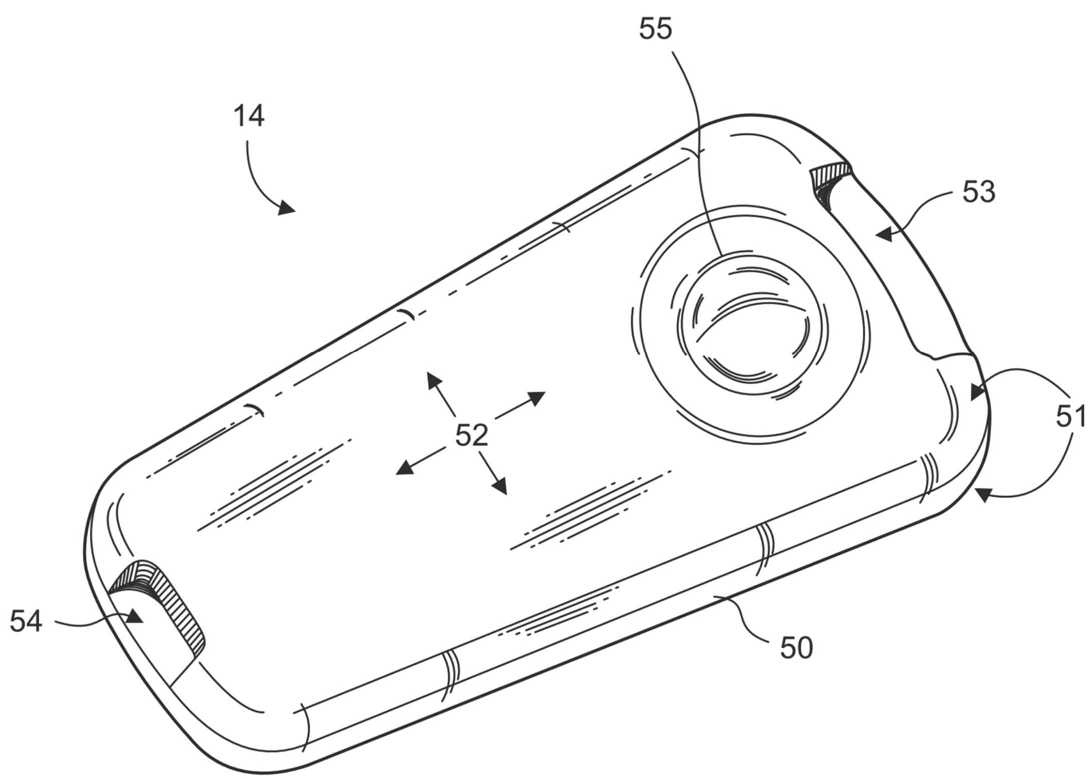


Fig. 6.

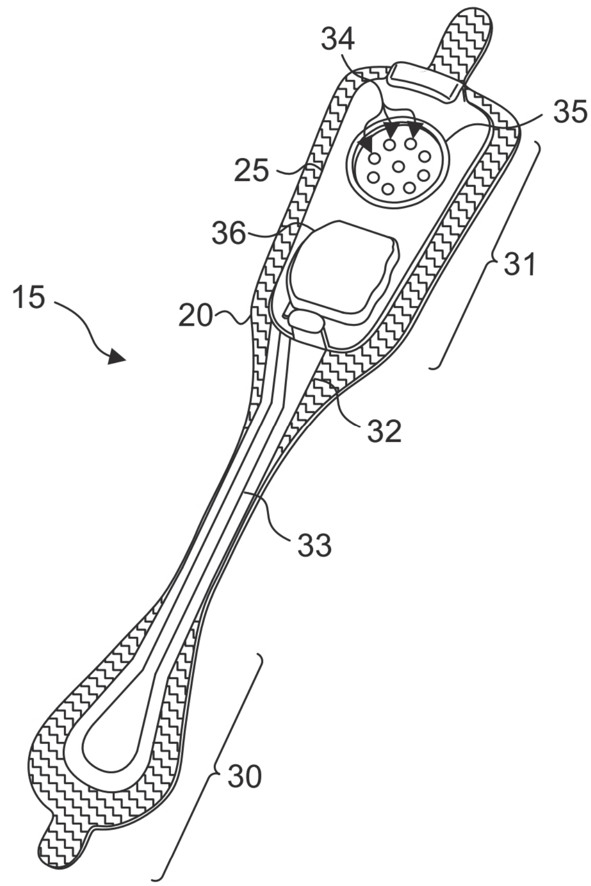


Fig. 7.

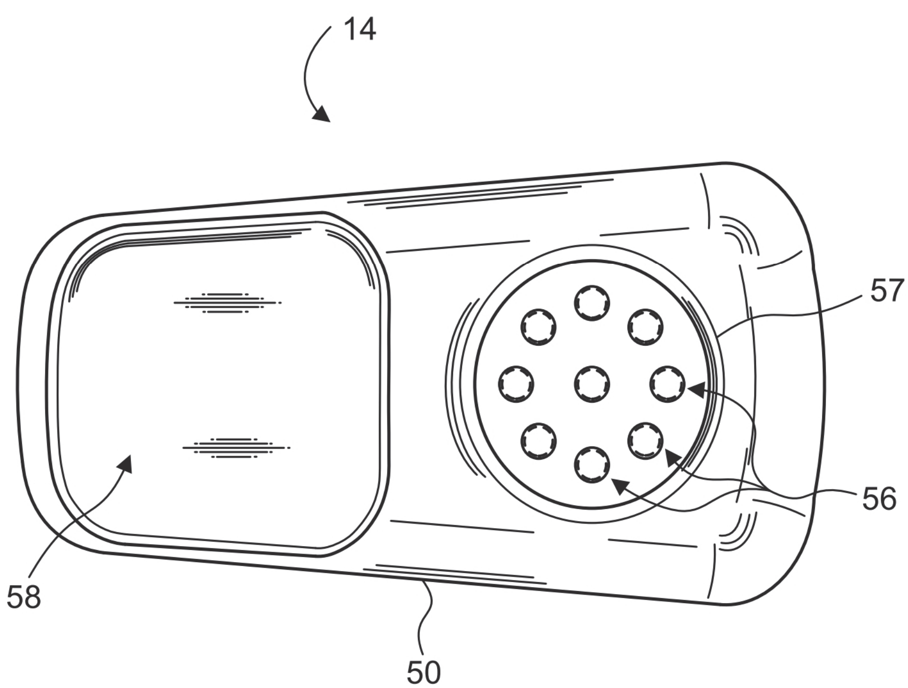


Fig. 8.

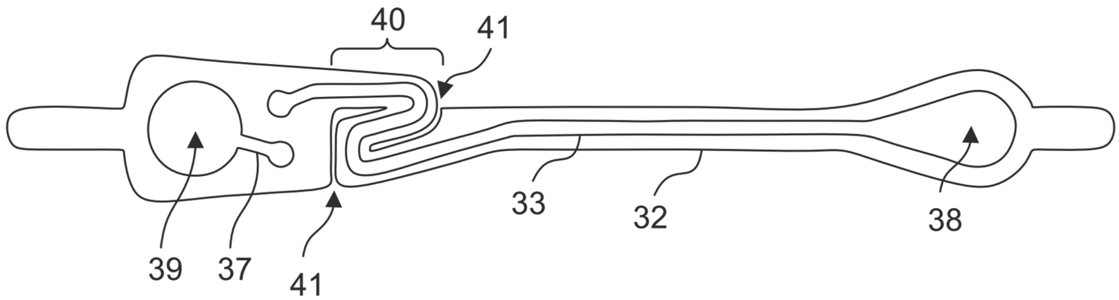


Fig. 9.

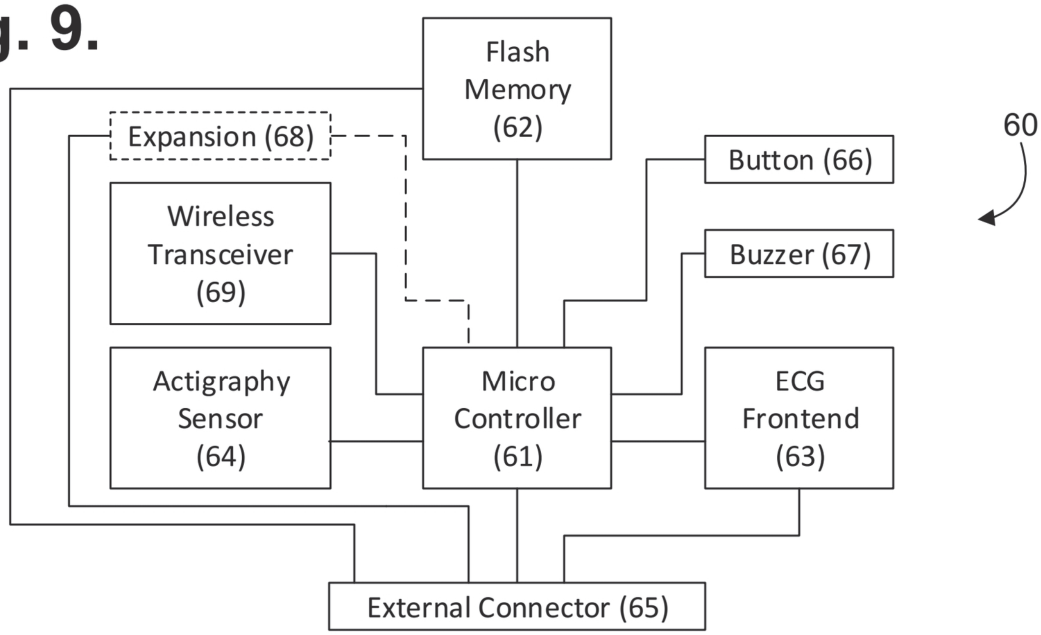


Fig. 10.

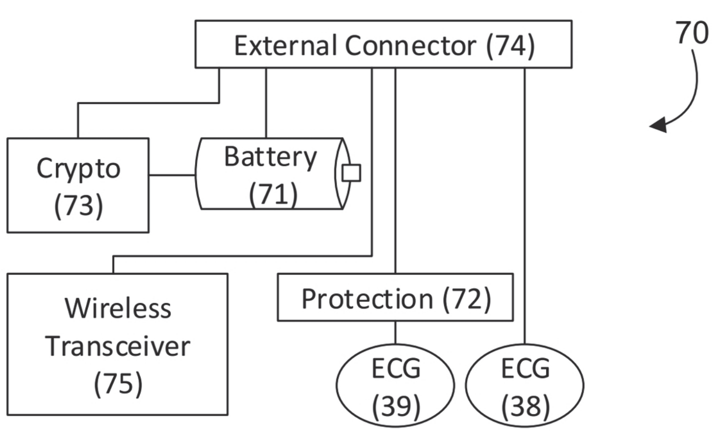


Fig. 11.

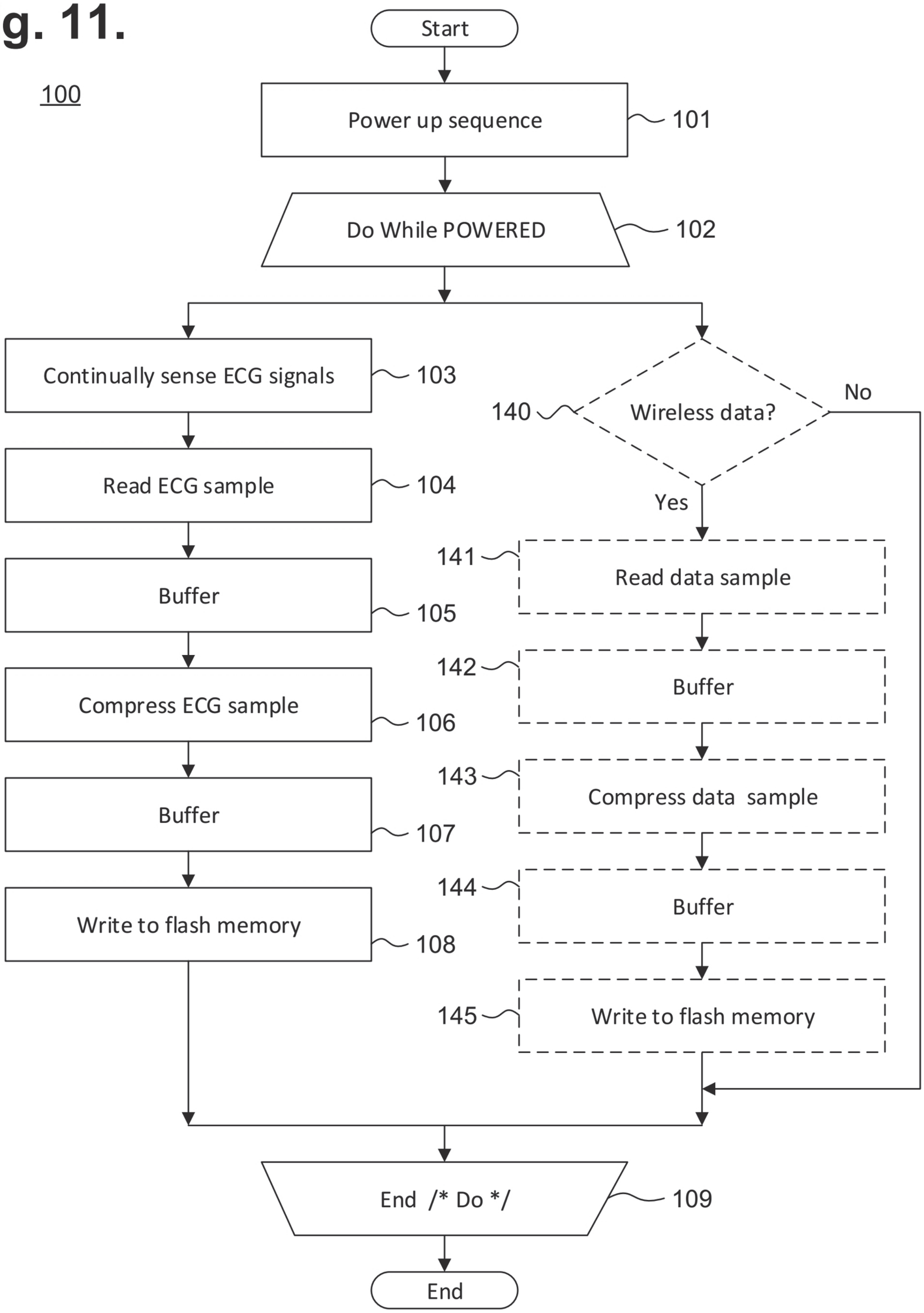

100
Start
Power up sequence
101
Do While POWERED
102
Continually sense ECG signals
103
Read ECG sample
104
Buffer
105
Compress ECG sample
106
Buffer
107
Write to flash memory
108
140
Wireless data?
No
Yes
141
Read data sample
142
Buffer
143
Compress data sample
144
Buffer
145
Write to flash memory
End /* Do */
109
End

Fig. 12.

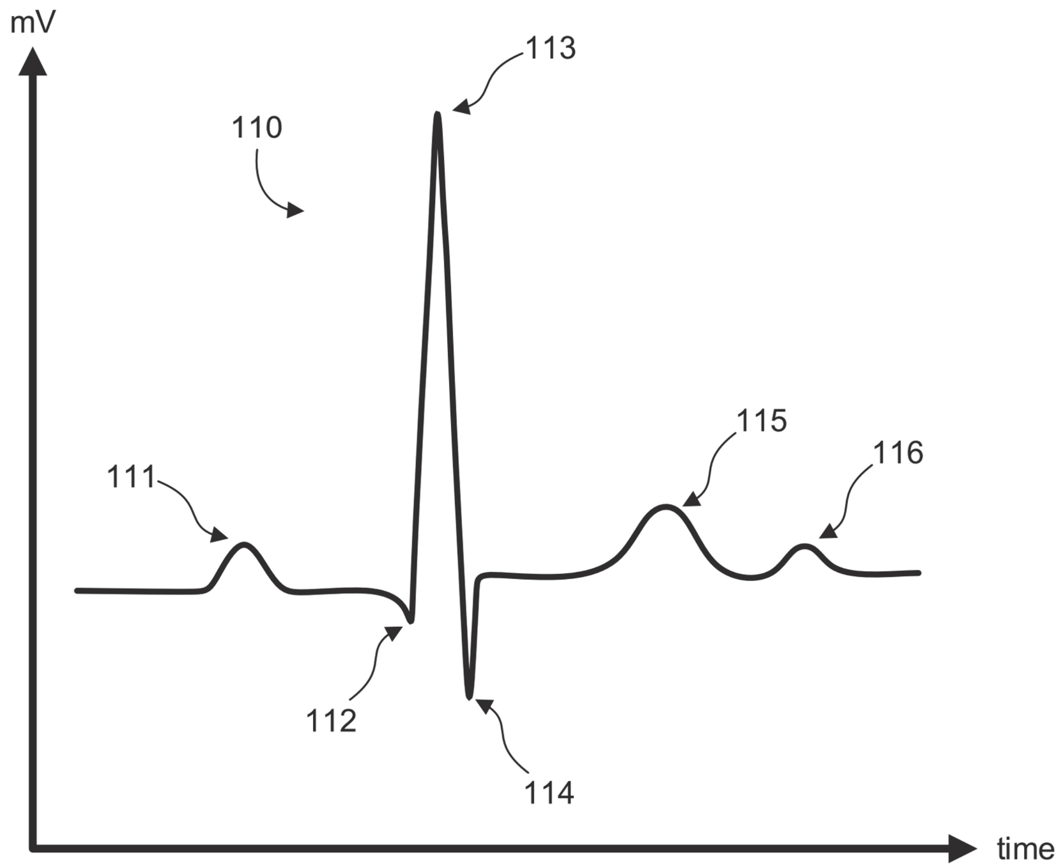
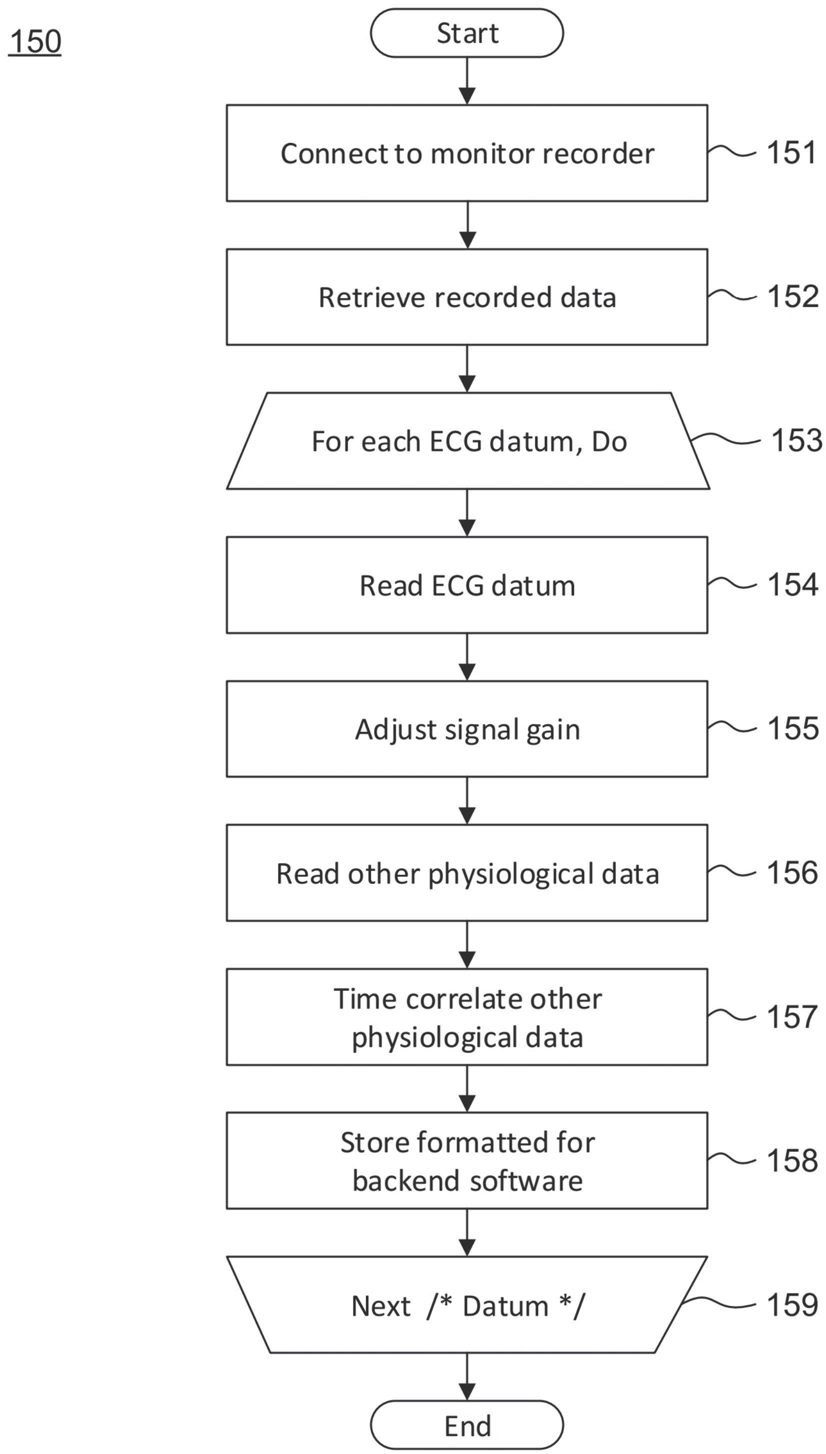


Fig. 13.


150
Start
Connect to monitor recorder
151
Retrieve recorded data
152
For each ECG datum, Do
153
Read ECG datum
154
Adjust signal gain
155
Read other physiological data
156
Time correlate other physiological data
157
Store formatted for backend software
158
Next /* Datum */
159
End

ELECTROCARDIOGRAPHY PATCH

PRIORITY CLAIM AND CROSS-REFERENCE TO RELATED APPLICATIONS

This application is a continuation of U.S. patent application Ser. No. 18/647,762, filed Apr. 26, 2024, titled ELECTROCARDIOGRAPHY PATCH, which is a continuation of U.S. patent application Ser. No. 18/353,398, filed Jul. 17, 2023, titled ELECTROCARDIOGRAPHY PATCH, which is a continuation of U.S. patent application Ser. No. 17/946,933, filed Sep. 16, 2022, titled ELECTROCARDIOGRAPHY PATCH, which is a continuation of U.S. patent application Ser. No. 17/367,476, filed Jul. 5, 2021, titled ELECTROCARDIOGRAPHY PATCH, which is a continuation of U.S. patent application Ser. No. 17/119,945, filed Dec. 11, 2020, titled ELECTROCARDIOGRAPHY PATCH, which is a continuation of U.S. patent application Ser. No. 16/241,929, filed Jan. 7, 2019, titled REMOTE INTERFACING ELECTROCARDIOGRAPHY PATCH, which is a continuation of U.S. patent application Ser. No. 15/818,437, filed Nov. 20, 2017, titled REMOTE INTERFACING ELECTROCARDIOGRAPHY PATCH, which is a continuation of U.S. patent application Ser. No. 15/256,266, filed Sep. 2, 2016, titled REMOTE INTERFACING OF EXTENDED WEAR ELECTROCARDIOGRAPHY AND PHYSIOLOGICAL SENSOR MONITOR, which is a continuation of U.S. patent application Ser. No. 14/082,071, filed Nov. 15, 2013, titled REMOTE INTERFACING OF EXTENDED WEAR ELECTROCARDIOGRAPHY AND PHYSIOLOGICAL SENSOR MONITOR, which is a continuation-in-part of U.S. patent application Ser. No. 14/080,717, filed Nov. 14, 2013, titled EXTENDED WEAR ELECTROCARDIOGRAPHY PATCH, which claims priority to U.S. Provisional Patent App. No. 61/882,403, filed Sep. 25, 2013, titled LONG-TERM WEARABLE PHYSIOLOGICAL MONITOR. U.S. patent application Ser. No. 14/082,071 is also a continuation-in-part of U.S. patent application Ser. No. 14/080,725, filed Nov. 14, 2013, titled EXTENDED WEAR AMBULATORY ELECTROCARDIOGRAPHY AND PHYSIOLOGICAL SENSOR MONITOR, which claims priority to U.S. Provisional Patent App. No. 61/882,403, filed Sep. 25, 2013, titled LONG-TERM WEARABLE PHYSIOLOGICAL MONITOR. The entire contents of these applications are incorporated by reference herein in their entirely and relied upon.

FIELD

This application relates in general to electrocardiographic monitoring and, in particular, to an electrocardiography patch.

BACKGROUND

The heart emits electrical signals as a by-product of the propagation of the action potentials that trigger depolarization of heart fibers. An electrocardiogram (ECG) measures and records such electrical potentials to visually depict the electrical activity of the heart over time. Conventionally, a standardized set format 12-lead configuration is used by an ECG machine to record cardiac electrical signals from well-established traditional chest locations. Electrodes at the end of each lead are placed on the skin over the anterior thoracic region of the patient's body to the lower right and to the lower left of the sternum, on the left anterior chest, and on the limbs. Sensed cardiac electrical activity is represented

by PQRSTU waveforms that can be interpreted post-ECG recordation to derive heart rate and physiology. The P-wave represents atrial electrical activity. The QRSTU components represent ventricular electrical activity.

An ECG is a tool used by physicians to diagnose heart problems and other potential health concerns. An ECG is a snapshot of heart function, typically recorded over 12 seconds, that can help diagnose rate and regularity of heartbeats, effect of drugs or cardiac devices, including pacemakers and implantable cardioverter-defibrillators (ICDs), and whether a patient has heart disease. ECGs are used in-clinic during appointments, and, as a result, are limited to recording only those heart-related aspects present at the time of recording. Sporadic conditions that may not show up during a spot ECG recording require other means to diagnose them. These disorders include fainting or syncope; rhythm disorders, such as tachyarrhythmias and bradyarrhythmias; apneic episodes; and other cardiac and related disorders. Thus, an ECG only provides a partial picture and can be insufficient for complete patient diagnosis of many cardiac disorders.

Diagnostic efficacy can be improved, when appropriate, through the use of long-term extended ECG monitoring. Recording sufficient ECG and related physiology over an extended period is challenging, and often essential to enabling a physician to identify events of potential concern. A 30-day observation period is considered the "gold standard" of ECG monitoring, yet achieving a 30-day observation day period has proven unworkable because such ECG monitoring systems are arduous to employ, cumbersome to the patient, and excessively costly. Ambulatory monitoring in-clinic is implausible and impracticable. Nevertheless, if a patient's ECG could be recorded in an ambulatory setting, thereby allowing the patient to engage in activities of daily living, the chances of acquiring meaningful information and capturing an abnormal event while the patient is engaged in normal activities becomes more likely to be achieved.

For instance, the long-term wear of ECG electrodes is complicated by skin irritation and the inability ECG electrodes to maintain continual skin contact after a day or two. Moreover, time, dirt, moisture, and other environmental contaminants, as well as perspiration, skin oil, and dead skin cells from the patient's body, can get between an ECG electrode, the non-conductive adhesive used to adhere the ECG electrode, and the skin's surface. All of these factors adversely affect electrode adhesion and the quality of cardiac signal recordings. Furthermore, the physical movements of the patient and their clothing impart various compressional, tensile, and torsional forces on the contact point of an ECG electrode, especially over long recording times, and an inflexibly fastened ECG electrode will be prone to becoming dislodged. Moreover, dislodgment may occur unbeknownst to the patient, making the ECG recordings worthless. Further, some patients may have skin that is susceptible to itching or irritation, and the wearing of ECG electrodes can aggravate such skin conditions. Thus, a patient may want or need to periodically remove or replace ECG electrodes during a long-term ECG monitoring period, whether to replace a dislodged electrode, reestablish better adhesion, alleviate itching or irritation, allow for cleansing of the skin, allow for showering and exercise, or for other purpose. Such replacement or slight alteration in electrode location actually facilitates the goal of recording the ECG signal for long periods of time.

Conventionally, Holter monitors are widely used for long-term extended ECG monitoring. Typically, they are used for only 24-48 hours. A typical Holter monitor is a wearable and

portable version of an ECG that include cables for each electrode placed on the skin and a separate battery-powered ECG recorder. The cable and electrode combination (or leads) are placed in the anterior thoracic region in a manner similar to what is done with an in-clinic standard ECG machine. The duration of a Holter monitoring recording depends on the sensing and storage capabilities of the monitor, as well as battery life. A "looping" Holter monitor (or event) can operate for a longer period of time by overwriting older ECG tracings, thence "recycling" storage in favor of extended operation, yet at the risk of losing event data. Although capable of extended ECG monitoring, Holter monitors are cumbersome, expensive and typically only available by medical prescription, which limits their usability. Further, the skill required to properly place the electrodes on the patient's chest hinders or precludes a patient from replacing or removing the precordial leads and usually involves moving the patient from the physician office to a specialized center within the hospital or clinic.

The ZIO XT Patch and ZIO Event Card devices, manufactured by iRhythm Tech., Inc., San Francisco, CA, are wearable stick-on monitoring devices that are typically worn on the upper left pectoral region to respectively provide continuous and looping ECG recording. The location is used to simulate surgically implanted monitors. Both of these devices are prescription-only and for single patient use. The ZIO XT Patch device is limited to a 14-day monitoring period, while the electrodes only of the ZIO Event Card device can be worn for up to 30 days. The ZIO XT Patch device combines both electronic recordation components, including battery, and physical electrodes into a unitary assembly that adheres to the patient's skin. The ZIO XT Patch device uses adhesive sufficiently strong to support the weight of both the monitor and the electrodes over an extended period of time and to resist disadherance from the patient's body, albeit at the cost of disallowing removal or relocation during the monitoring period. Moreover, throughout monitoring, the battery is continually depleted and battery capacity can potentially limit overall monitoring duration. The ZIO Event Card device is a form of downsized Holter monitor with a recorder component that must be removed temporarily during baths or other activities that could damage the non-waterproof electronics. Both devices represent compromises between length of wear and quality of ECG monitoring, especially with respect to ease of long term use, female-friendly fit, and quality of atrial (P-wave) signals.

In addition, with the advent of wireless communications and wearable computing, other types of personal ambulatory monitors, of varying degrees of sophistication, have become increasingly available. For example, adherents to the so-called "Quantified Self" movement combine wearable sensors and wearable computing to self-track activities of their daily lives, including inputs, states, and performance. The Nike+FuelBand, manufactured by Nike Inc., Beaverton, OR, for instance, provides an activity tracker that is worn on the wrist and allows the wearer to temporally track the number of foot steps taken each day and an estimation of the calories burned. The activity tracker can interface with a smart phone device to allow a wearer to monitor their progress towards a fitness goal. Such quantified physiology, however, is typically tracked for only the personal use of the wearer and is not time-correlated to physician-supervised monitoring.

Therefore, a need remains for an extended wear continuously recording ECG monitor practically capable of being worn for a long period of time in both men and women and capable of recording atrial signals reliably.

A further need remains for facilities to integrate wider-ranging physiological and "life tracking"-type data into long-term ECG and physiological data monitoring.

SUMMARY

Physiological monitoring can be provided through a wearable monitor that includes two components, a flexible extended wear electrode patch and a removable reusable monitor recorder. The wearable monitor sits centrally (in the midline) on the patient's chest along the sternum oriented top-to-bottom. The placement of the wearable monitor in a location at the sternal midline (or immediately to either side of the sternum), with its unique narrow "hourglass"-like shape, benefits long-term extended wear by removing the requirement that ECG electrodes be continually placed in the same spots on the skin throughout the monitoring period. Instead, the patient is free to place an electrode patch anywhere within the general region of the sternum, the area most likely to record high quality atrial signals or P-waves. The wearable monitor can also interoperate wirelessly with other wearable physiology and activity sensors and with wearable or mobile communications devices, including so-called "smart phones," to download monitoring data either in real-time or in batches. The monitor recorder can also be equipped with a wireless transceiver to either provide data or other information to, or receive data or other information from, an interfacing wearable physiology and activity sensor, or wearable or mobile communications devices for relay to a further device, such as a server, analysis, or other purpose.

One embodiment provides a remotely-interfaceable electrocardiography patch. The remotely-interfaceable electrocardiography patch includes a backing formed of a strip of material and an electrocardiographic electrode on each end of the backing to capture electrocardiographic signals. A flexible circuit includes a pair of circuit traces electrically coupled to the electrocardiographic electrodes. A wireless transceiver communicates at least one of the electrocardiographic signals and other physiological measures with one or more of a physiology and activity sensor, communication device, server, and personal computer.

A further embodiment provides an electrocardiography patch. The patch includes a backing and at least two electrocardiographic electrodes each positioned on the backing, across from another of the electrocardiographic electrodes, to capture electrocardiographic signals. A flexible circuit includes a pair of circuit traces electrically coupled to the electrocardiographic electrodes. A wireless transceiver communicates at least a portion of the electrocardiographic signals.

A still further embodiment provides an apparatus. A strip has first and second end sections, and a first surface and second surface. Two electrocardiographic electrodes are provided on the strip with one of the electrocardiographic electrodes provided on the first surface of the first end section of the strip and another of the electrocardiographic electrodes positioned on the first surface on the second end section of the strip. A flexible circuit is mounted to the second surface of the strip and includes a circuit trace electrically coupled to each of the electrocardiographic electrodes. A wireless transceiver is affixed on one of the first or second end sections, and a battery is positioned on one of

the first or second end sections. A processor is positioned on one of the first or second end sections and is housed separate from the battery.

The monitoring patch is especially suited to the female anatomy. The narrow longitudinal midsection can fit nicely within the intermammary cleft of the breasts without inducing discomfort, whereas conventional patch electrodes are wide and, if adhesed between the breasts, would cause chafing, irritation, frustration, and annoyance, leading to low patient compliance.

The foregoing aspects enhance ECG monitoring performance and quality, facilitating long-term ECG recording, critical to accurate arrhythmia diagnosis.

In addition, the foregoing aspects enhance comfort in women (and certain men), but not irritation of the breasts, by placing the monitoring patch in the best location possible for optimizing the recording of cardiac signals from the atrium, another feature critical to proper arrhythmia diagnosis.

Finally, the foregoing aspects as relevant to monitoring are equally applicable to recording other physiological measures, such as temperature, respiratory rate, blood sugar, oxygen saturation, and blood pressure, as well as other measures of body chemistry and physiology.

Still other embodiments will become readily apparent to those skilled in the art from the following detailed description, wherein are described embodiments by way of illustrating the best mode contemplated. As will be realized, other and different embodiments are possible and the embodiments' several details are capable of modifications in various obvious respects, all without departing from their spirit and the scope. Accordingly, the drawings and detailed description are to be regarded as illustrative in nature and not as restrictive.

BRIEF DESCRIPTION OF THE DRAWINGS

FIGS. **1** and **2** are diagrams showing, by way of examples, an extended wear electrocardiography and physiological sensor monitor respectively fitted to the sternal region of a female patient and a male patient.

FIG. **3** is a functional block diagram showing a system for remote interfacing of an extended wear electrocardiography and physiological sensor monitor in accordance with one embodiment.

FIG. **4** is a perspective view showing an extended wear electrode patch with a monitor recorder inserted.

FIG. **5** is a perspective view showing the monitor recorder of FIG. **4**.

FIG. **6** is a perspective view showing the extended wear electrode patch of FIG. **4** without a monitor recorder inserted.

FIG. **7** is a bottom plan view of the monitor recorder of FIG. **4**.

FIG. **8** is a top view showing the flexible circuit of the extended wear electrode patch of FIG. **4** when mounted above the flexible backing.

FIG. **9** is a functional block diagram showing the component architecture of the circuitry of the monitor recorder of FIG. **4**.

FIG. **10** is a functional block diagram showing the circuitry of the extended wear electrode patch of FIG. **4**.

FIG. **11** is a flow diagram showing a monitor recorder-implemented method for monitoring ECG data for use in the monitor recorder of FIG. **4**.

FIG. **12** is a graph showing, by way of example, a typical ECG waveform.

FIG. **13** is a flow diagram showing a method for offloading and converting ECG and other physiological data from an extended wear electrocardiography and physiological sensor monitor in accordance with one embodiment.

DETAILED DESCRIPTION

Physiological monitoring can be provided through a wearable monitor that includes two components, a flexible extended wear electrode patch and a removable reusable monitor recorder. FIGS. **1** and **2** are diagrams showing, by way of examples, an extended wear electrocardiography and physiological sensor monitor **12**, including a monitor recorder **14** in accordance with one embodiment, respectively fitted to the sternal region of a female patient **10** and a male patient **11**. The wearable monitor **12** sits centrally (in the midline) on the patient's chest along the sternum **13** oriented top-to-bottom with the monitor recorder **14** preferably situated towards the patient's head. In a further embodiment, the orientation of the wearable monitor **12** can be corrected post-monitoring, as further described infra. The electrode patch **15** is shaped to fit comfortably and conformal to the contours of the patient's chest approximately centered on the sternal midline **16** (or immediately to either side of the sternum **13**). The distal end of the electrode patch **15** extends towards the Xiphoid process and, depending upon the patient's build, may straddle the region over the Xiphoid process. The proximal end of the electrode patch **15**, located under the monitor recorder **14**, is below the manubrium and, depending upon patient's build, may straddle the region over the manubrium.

The placement of the wearable monitor **12** in a location at the sternal midline **16** (or immediately to either side of the sternum **13**) significantly improves the ability of the wearable monitor **12** to cutaneously sense cardiac electric signals, particularly the P-wave (or atrial activity) and, to a lesser extent, the QRS interval signals in the ECG waveforms that indicate ventricular activity, while simultaneously facilitating comfortable long-term wear for many weeks. The sternum **13** overlies the right atrium of the heart and the placement of the wearable monitor **12** in the region of the sternal midline **13** puts the ECG electrodes of the electrode patch **15** in a location better adapted to sensing and recording P-wave signals than other placement locations, say, the upper left pectoral region or lateral thoracic region or the limb leads. In addition, placing the lower or inferior pole (ECG electrode) of the electrode patch **15** over (or near) the Xiphoid process facilitates sensing of ventricular activity and provides superior recordation of the QRS interval.

When operated standalone, the monitor recorder **14** of the extended wear electrocardiography and physiological sensor monitor **12** senses and records the patient's ECG data into an onboard memory. In addition, the wearable monitor **12** can interoperate with other devices. FIG. **3** is a functional block diagram showing a system **120** for remote interfacing of an extended wear electrocardiography and physiological sensor monitor **12** in accordance with one embodiment. The monitor recorder **14** is a reusable component that can be fitted during patient monitoring into a non-conductive receptacle provided on the electrode patch **15**, as further described infra with reference to FIG. **4**, and later removed for offloading of stored ECG data or to receive revised programming. The monitor recorder **14** can then be connected to a download station **125**, which could be a programmer or other device that permits the retrieval of stored ECG monitoring data, execution of diagnostics on or programming of the monitor recorder **14**, or performance of other functions. The monitor

recorder **14** has a set of electrical contacts (not shown) that enable the monitor recorder **14** to physically interface to a set of terminals **128** on a paired receptacle **127** of the download station **125**. In turn, the download station **125** executes a communications or offload program **126** ("Offload") or similar program that interacts with the monitor recorder **14** via the physical interface to retrieve the stored ECG monitoring data. The download station **125** could be a server, personal computer, tablet or handheld computer, smart mobile device, or purpose-built programmer designed specific to the task of interfacing with a monitor recorder **14**. Still other forms of download station **125** are possible.

Upon retrieving stored ECG monitoring data from a monitor recorder **14**, middleware first operates on the retrieved data to adjust the ECG capture quality, as necessary, and to convert the retrieved data into a format suitable for use by third party post-monitoring analysis software, as further described infra with reference to FIG. **13**. The formatted data can then be retrieved from the download station **125** over a hard link **135** using a control program **137** ("Ctl") or analogous application executing on a personal computer **136** or other connectable computing device, via a communications link (not shown), whether wired or wireless, or by physical transfer of storage media (not shown). The personal computer **136** or other connectable device may also execute middleware that converts ECG data and other information into a format suitable for use by a third-party post-monitoring analysis program, as further described infra with reference to FIG. **13**. Note that formatted data stored on the personal computer **136** would have to be maintained and safeguarded in the same manner as electronic medical records (EMRs) **134** in the secure database **124**, as further discussed infra. In a further embodiment, the download station **125** is able to directly interface with other devices over a computer communications network **121**, which could be some combination of a local area network and a wide area network, including the Internet, over a wired or wireless connection.

A client-server model could be used to employ a server **122** to remotely interface with the download station **125** over the network **121** and retrieve the formatted data or other information. The server **122** executes a patient management program **123** ("Mgt") or similar application that stores the retrieved formatted data and other information in a secure database **124** cataloged in that patient's EMRs **134**. In addition, the patient management program **123** could manage a subscription service that authorizes a monitor recorder **14** to operate for a set period of time or under pre-defined operational parameters.

The patient management program **123**, or other trusted application, also maintains and safeguards the secure database **124** to limit access to patient EMRs **134** to only authorized parties for appropriate medical or other uses, such as mandated by state or federal law, such as under the Health Insurance Portability and Accountability Act (HIPAA) or per the European Union's Data Protection Directive. For example, a physician may seek to review and evaluate his patient's ECG monitoring data, as securely stored in the secure database **124**. The physician would execute an application program **130** ("Pgm"), such as a post-monitoring ECG analysis program, on a personal computer **129** or other connectable computing device, and, through the application **130**, coordinate access to his patient's EMRs **134** with the patient management program **123**. Other schemes and safeguards to protect and maintain the integrity of patient EMRs **134** are possible.

The wearable monitor **12** can interoperate wirelessly with other wearable physiology and activity sensors **131** and with wearable or mobile communications devices **133**. Wearable physiology and activity sensors **131** encompass a wide range of wirelessly interconnectable devices that measure or monitor data physical to the patient's body, such as heart rate, temperature, blood pressure, and so forth; physical states, such as movement, sleep, footsteps, and the like; and performance, including calories burned or estimated blood glucose level. These devices originate both within the medical community to sense and record traditional medical physiology that could be useful to a physician in arriving at a patient diagnosis or clinical trajectory, as well as from outside the medical community, from, for instance, sports or lifestyle product companies who seek to educate and assist individuals with self-quantifying interests.

Frequently, wearable physiology and activity sensors **131** are capable of wireless interfacing with wearable or mobile communications devices **133**, particularly smart mobile devices, including so-called "smart phones," to download monitoring data either in real-time or in batches. The wearable or mobile communications device **133** executes an application ("App") that can retrieve the data collected by the wearable physiology and activity sensor **131** and evaluate the data to generate information of interest to the wearer, such as an estimation of the effectiveness of the wearer's exercise efforts. Still other wearable or mobile communications device **133** functions on the collected data are possible.

The wearable or mobile communications devices **133** could also serve as a conduit for providing the data collected by the wearable physiology and activity sensor **131** to a server **122**, or, similarly, the wearable physiology and activity sensor **131** could itself directly provide the collected data to the server **122**. The server **122** could then merge the collected data into the wearer's EMRs **134** in the secure database **124**, if appropriate (and permissible), or the server **122** could perform an analysis of the collected data, perhaps based by comparison to a population of like wearers of the wearable physiology and activity sensor **131**. Still other server **122** functions on the collected data are possible.

Finally, the monitor recorder **14** can also be equipped with a wireless transceiver, as further described infra with reference to FIGS. **9** and **10**. Thus, when wireless-enabled, both wearable physiology and activity sensors **131** and wearable or mobile communications devices **133** could wirelessly interface with the monitor recorder **14**, which could either provide data or other information to, or receive data or other information from an interfacing device for relay to a further device, such as the server **122**, analysis, or other purpose. In addition, the monitor recorder **14** could wirelessly interface directly with the server **122**, personal computer **129**, or other computing device connectable over the network **121**, when the monitor recorder **14** is appropriately equipped for interfacing with such devices. Still other types of remote interfacing of the monitor recorder **14** are possible.

During use, the electrode patch **15** is first adhered to the skin along the sternal midline **16** (or immediately to either side of the sternum **13**). A monitor recorder **14** is then snapped into place on the electrode patch **15** to initiate ECG monitoring. FIG. **4** is a perspective view showing an extended wear electrode patch **15** with a monitor recorder **14** in accordance with one embodiment inserted. The body of the electrode patch **15** is preferably constructed using a flexible backing **20** formed as an elongated strip **21** of wrap knit or similar stretchable material with a narrow longitudinal mid-section **23** evenly tapering inward from both sides. A pair of cut-outs **22** between the distal and proximal

ends of the electrode patch **15** create a narrow longitudinal midsection **23** or "isthmus" and defines an elongated "hourglass"-like shape, when viewed from above.

The electrode patch **15** incorporates features that significantly improve wearability, performance, and patient comfort throughout an extended monitoring period. During wear, the electrode patch **15** is susceptible to pushing, pulling, and torqueing movements, including compressional and torsional forces when the patient bends forward, and tensile and torsional forces when the patient leans backwards. To counter these stress forces, the electrode patch **15** incorporates strain and crimp reliefs, such as described in commonly-assigned U.S. Patent, entitled "Extended Wear Electrocardiography Patch," U.S. Pat. No. 9,545,204, issued Jan. 17, 2017, the disclosure of which is incorporated by reference. In addition, the cut-outs **22** and longitudinal midsection **23** help minimize interference with and discomfort to breast tissue, particularly in women (and gynecomastic men). The cut-outs **22** and longitudinal midsection **23** further allow better conformity of the electrode patch **15** to sternal bowing and to the narrow isthmus of flat skin that can occur along the bottom of the intermammary cleft between the breasts, especially in buxom women. The cut-outs **22** and longitudinal midsection **23** help the electrode patch **15** fit nicely between a pair of female breasts in the intermammary cleft. Still other shapes, cut-outs and conformities to the electrode patch **15** are possible.

The monitor recorder **14** removably and reusably snaps into an electrically non-conductive receptacle **25** during use. The monitor recorder **14** contains electronic circuitry for recording and storing the patient's electrocardiography as sensed via a pair of ECG electrodes provided on the electrode patch **15**, such as described in commonly-assigned U.S. Patent, entitled "Extended Wear Ambulatory Electrocardiography and Physiological Sensor Monitor," U.S. Pat. No. 9,730,593, issued Aug. 15, 2017, the disclosure which is incorporated by reference. The non-conductive receptacle **25** is provided on the top surface of the flexible backing **20** with a retention catch **26** and tension clip **27** molded into the non-conductive receptacle **25** to conformably receive and securely hold the monitor recorder **14** in place.

The monitor recorder **14** includes a sealed housing that snaps into place in the non-conductive receptacle **25**. FIG. **5** is a perspective view showing the monitor recorder **14** of FIG. **4**. The sealed housing **50** of the monitor recorder **14** intentionally has a rounded isosceles trapezoidal-like shape **52**, when viewed from above, such as described in commonly-assigned U.S. Design Patent, entitled "Electrocardiography Monitor," No. D717,955, issued Nov. 18, 2014, the disclosure of which is incorporated by reference. The edges **51** along the top and bottom surfaces are rounded for patient comfort. The sealed housing **50** is approximately 47 mm long, 23 mm wide at the widest point, and 7 mm high, excluding a patient-operable tactile-feedback button **55**. The sealed housing **50** can be molded out of polycarbonate, ABS, or an alloy of those two materials. The button **55** is waterproof and the button's top outer surface is molded silicon rubber or similar soft pliable material. A retention detent **53** and tension detent **54** are molded along the edges of the top surface of the housing **50** to respectively engage the retention catch **26** and the tension clip **27** molded into non-conductive receptacle **25**. Other shapes, features, and conformities of the sealed housing **50** are possible.

The electrode patch **15** is intended to be disposable. The monitor recorder **14**, however, is reusable and can be transferred to successive electrode patches **15** to ensure continuity of monitoring. The placement of the wearable monitor **12** in a location at the sternal midline **16** (or immediately to either side of the sternum **13**) benefits long-term extended wear by removing the requirement that ECG electrodes be continually placed in the same spots on the skin throughout the monitoring period. Instead, the patient is free to place an electrode patch **15** anywhere within the general region of the sternum **13**.

As a result, at any point during ECG monitoring, the patient's skin is able to recover from the wearing of an electrode patch **15**, which increases patient comfort and satisfaction, while the monitor recorder **14** ensures ECG monitoring continuity with minimal effort. A monitor recorder **14** is merely unsnapped from a worn out electrode patch **15**, the worn out electrode patch **15** is removed from the skin, a new electrode patch **15** is adhered to the skin, possibly in a new spot immediately adjacent to the earlier location, and the same monitor recorder **14** is snapped into the new electrode patch **15** to reinitiate and continue the ECG monitoring.

During use, the electrode patch **15** is first adhered to the skin in the sternal region. FIG. **6** is a perspective view showing the extended wear electrode patch **15** of FIG. **4** without a monitor recorder **14** inserted. A flexible circuit **32** is adhered to each end of the flexible backing **20**. A distal circuit trace **33** and a proximal circuit trace (not shown) electrically couple ECG electrodes (not shown) to a pair of electrical pads **34**. The electrical pads **34** are provided within a moisture-resistant seal **35** formed on the bottom surface of the non-conductive receptacle **25**. When the monitor recorder **14** is securely received into the non-conductive receptacle **25**, that is, snapped into place, the electrical pads **34** interface to electrical contacts (not shown) protruding from the bottom surface of the monitor recorder **14**, and the moisture-resistant seal **35** enables the monitor recorder **14** to be worn at all times, even during bathing or other activities that could expose the monitor recorder **14** to moisture.

In addition, a battery compartment **36** is formed on the bottom surface of the non-conductive receptacle **25**, and a pair of battery leads (not shown) electrically interface the battery to another pair of the electrical pads **34**. The battery contained within the battery compartment **35** can be replaceable, rechargeable or disposable.

The monitor recorder **14** draws power externally from the battery provided in the non-conductive receptacle **25**, thereby uniquely obviating the need for the monitor recorder **14** to carry a dedicated power source. FIG. **7** is a bottom plan view of the monitor recorder **14** of FIG. **4**. A cavity **58** is formed on the bottom surface of the sealed housing **50** to accommodate the upward projection of the battery compartment **36** from the bottom surface of the non-conductive receptacle **25**, when the monitor recorder **14** is secured in place on the non-conductive receptacle **25**. A set of electrical contacts **56** protrude from the bottom surface of the sealed housing **50** and are arranged in alignment with the electrical pads **34** provided on the bottom surface of the non-conductive receptacle **25** to establish electrical connections between the electrode patch **15** and the monitor recorder **14**. In addition, a seal coupling **57** circumferentially surrounds the set of electrical contacts **56** and securely mates with the moisture-resistant seal **35** formed on the bottom surface of the non-conductive receptacle **25**.

The placement of the flexible backing **20** on the sternal midline **16** (or immediately to either side of the sternum **13**) also helps to minimize the side-to-side movement of the wearable monitor **12** in the left- and right-handed directions during wear. To counter the dislodgment of the flexible backing **20** due to compressional and torsional forces, a

layer of non-irritating adhesive, such as hydrocolloid, is provided at least partially on the underside, or contact, surface of the flexible backing **20**, but only on the distal end **30** and the proximal end **31**. As a result, the underside, or contact surface of the longitudinal midsection **23** does not have an adhesive layer and remains free to move relative to the skin. Thus, the longitudinal midsection **23** forms a crimp relief that respectively facilitates compression and twisting of the flexible backing **20** in response to compressional and torsional forces. Other forms of flexible backing crimp reliefs are possible.

Unlike the flexible backing **20**, the flexible circuit **32** is only able to bend and cannot stretch in a planar direction. The flexible circuit **32** can be provided either above or below the flexible backing **20**. FIG. **8** is a top view showing the flexible circuit **32** of the extended wear electrode patch **15** of FIG. **4** when mounted above the flexible backing **20**. A distal ECG electrode **38** and proximal ECG electrode **39** are respectively coupled to the distal and proximal ends of the flexible circuit **32**. A strain relief **40** is defined in the flexible circuit **32** at a location that is partially underneath the battery compartment **36** when the flexible circuit **32** is affixed to the flexible backing **20**. The strain relief **40** is laterally extendable to counter dislodgment of the ECG electrodes **38**, **39** due to tensile and torsional forces. A pair of strain relief cutouts **41** partially extend transversely from each opposite side of the flexible circuit **32** and continue longitudinally towards each other to define in 'S'-shaped pattern, when viewed from above. The strain relief respectively facilitates longitudinal extension and twisting of the flexible circuit **32** in response to tensile and torsional forces. Other forms of circuit board strain relief are possible.

ECG monitoring and other functions performed by the monitor recorder **14** are provided through a micro controlled architecture. FIG. **9** is a functional block diagram showing the component architecture of the circuitry **60** of the monitor recorder **14** of FIG. **4**. The circuitry **60** is externally powered through a battery provided in the non-conductive receptacle **25** (shown in FIG. **6**). Both power and raw ECG signals, which originate in the pair of ECG electrodes **38**, **39** (shown in FIG. **8**) on the distal and proximal ends of the electrode patch **15**, are received through an external connector **65** that mates with a corresponding physical connector on the electrode patch **15**. The external connector **65** includes the set of electrical contacts **56** that protrude from the bottom surface of the sealed housing **50** and which physically and electrically interface with the set of pads **34** provided on the bottom surface of the non-conductive receptacle **25**. The external connector includes electrical contacts **56** for data download, microcontroller communications, power, analog inputs, and a peripheral expansion port. The arrangement of the pins on the electrical connector **65** of the monitor recorder **14** and the device into which the monitor recorder **14** is attached, whether an electrode patch **15** or download station (not shown), follow the same electrical pin assignment convention to facilitate interoperability. The external connector **65** also serves as a physical interface to a download station that permits the retrieval of stored ECG monitoring data, communication with the monitor recorder **14**, and performance of other functions.

Operation of the circuitry **60** of the monitor recorder **14** is managed by a microcontroller **61**. The micro-controller **61** includes a program memory unit containing internal flash memory that is readable and writeable. The internal flash memory can also be programmed externally. The microcontroller **61** draws power externally from the battery provided on the electrode patch **15** via a pair of the electrical contacts **56**. The microcontroller **61** connects to the ECG front end circuit **63** that measures raw cutaneous electrical signals and generates an analog ECG signal representative of the electrical activity of the patient's heart over time.

The circuitry **60** of the monitor recorder **14** also includes a flash memory **62**, which the micro-controller **61** uses for storing ECG monitoring data and other physiology and information. The flash memory **62** also draws power externally from the battery provided on the electrode patch **15** via a pair of the electrical contacts **56**. Data is stored in a serial flash memory circuit, which supports read, erase and program operations over a communications bus. The flash memory **62** enables the microcontroller **61** to store digitized ECG data. The communications bus further enables the flash memory **62** to be directly accessed externally over the external connector **65** when the monitor recorder **14** is interfaced to a download station.

The circuitry **60** of the monitor recorder **14** further includes an actigraphy sensor **64** implemented as a 3-axis accelerometer. The accelerometer may be configured to generate interrupt signals to the microcontroller **61** by independent initial wake up and free fall events, as well as by device position. In addition, the actigraphy provided by the accelerometer can be used during post-monitoring analysis to correct the orientation of the monitor recorder **14** if, for instance, the monitor recorder **14** has been inadvertently installed upside down, that is, with the monitor recorder **14** oriented on the electrode patch **15** towards the patient's feet, as well as for other event occurrence analyses, such as described in commonly-assigned U.S. Pat. No. 9,737,224, issued Aug. 22, 2017, the disclosure of which is incorporated by reference.

The circuitry **60** of the monitor recorder **14** includes a wireless transceiver **69** that can provides wireless interfacing capabilities. The wireless transceiver **69** also draws power externally from the battery provided on the electrode patch **15** via a pair of the electrical contacts **56**. The wireless transceiver **69** can be implemented using one or more forms of wireless communications, including the IEEE 802.11 computer communications standard, that is Wi-Fi; the 4G mobile phone mobile communications standard; the Bluetooth data exchange standard; or other wireless communications or data exchange standards and protocols. The type of wireless interfacing capability could limit the range of interoperability of the monitor recorder **14**; for instance, Bluetooth-based implementations are designed for low power consumption with a short communications range.

The microcontroller **61** includes an expansion port that also utilizes the communications bus. External devices, separately drawing power externally from the battery provided on the electrode patch **15** or other source, can interface to the microcontroller **61** over the expansion port in half duplex mode. For instance, an external physiology sensor can be provided as part of the circuitry **60** of the monitor recorder **14**, or can be provided on the electrode patch **15** with communication with the micro-controller **61** provided over one of the electrical contacts **56**. The physiology sensor can include an SpO_2 sensor, blood pressure sensor, temperature sensor, respiratory rate sensor, glucose sensor, airflow sensor, volumetric pressure sensing, or other types of sensor or telemetric input sources. For instance, the integration of an airflow sensor is described in commonly-assigned U.S. Pat. No. 9,364,155, issued Jun. 14, 2016, the disclosure which is incorporated by reference.

Finally, the circuitry **60** of the monitor recorder **14** includes patient-interfaceable components, including a tactile feedback button **66**, which a patient can press to mark

events or to perform other functions, and a buzzer **67**, such as a speaker, magnetic resonator or piezoelectric buzzer. The buzzer **67** can be used by the microcontroller **61** to output feedback to a patient such as to confirm power up and initiation of ECG monitoring. Still other components as part of the circuitry **60** of the monitor recorder **14** are possible.

While the monitor recorder **14** operates under micro control, most of the electrical components of the electrode patch **15** operate passively. FIG. **10** is a functional block diagram showing the circuitry **70** of the extended wear electrode patch **15** of FIG. **4**. The circuitry **70** of the electrode patch **15** is electrically coupled with the circuitry **60** of the monitor recorder **14** through an external connector **74**. The external connector **74** is terminated through the set of pads **34** provided on the bottom of the non-conductive receptacle **25**, which electrically mate to corresponding electrical contacts **56** protruding from the bottom surface of the sealed housing **50** to electrically interface the monitor recorder **14** to the electrode patch **15**.

The circuitry **70** of the electrode patch **15** performs three primary functions. First, a battery **71** is provided in a battery compartment formed on the bottom surface of the non-conductive receptacle **25**. The battery **71** is electrically interfaced to the circuitry **60** of the monitor recorder **14** as a source of external power. The unique provisioning of the battery **71** on the electrode patch **15** provides several advantages. First, the locating of the battery **71** physically on the electrode patch **15** lowers the center of gravity of the overall wearable monitor **12** and thereby helps to minimize shear forces and the effects of movements of the patient and clothing. Moreover, the housing **50** of the monitor recorder **14** is sealed against moisture and providing power externally avoids having to either periodically open the housing **50** for the battery replacement, which also creates the potential for moisture intrusion and human error, or to recharge the battery, which can potentially take the monitor recorder **14** off line for hours at a time. In addition, the electrode patch **15** is intended to be disposable, while the monitor recorder **14** is a reusable component. Each time that the electrode patch **15** is replaced, a fresh battery is provided for the use of the monitor recorder **14**, which enhances ECG monitoring performance quality and duration of use. Finally, the architecture of the monitor recorder **14** is open, in that other physiology sensors or components can be added by virtue of the expansion port of the microcontroller **61**. Requiring those additional sensors or components to draw power from a source external to the monitor recorder **14** keeps power considerations independent of the monitor recorder **14**. Thus, a battery of higher capacity could be introduced when needed to support the additional sensors or components without effecting the monitor recorders circuitry **60**.

Second, the pair of ECG electrodes **38**, **39** respectively provided on the distal and proximal ends of the flexible circuit **32** are electrically coupled to the set of pads **34** provided on the bottom of the non-conductive receptacle **25** by way of their respective circuit traces **33**, **37**. The signal ECG electrode **39** includes a protection circuit **72**, which is an inline resistor that protects the patient from excessive leakage current.

Last, in a further embodiment, the circuitry **70** of the electrode patch **15** includes a cryptographic circuit **73** to authenticate an electrode patch **15** for use with a monitor recorder **14**. The cryptographic circuit **73** includes a device capable of secure authentication and validation. The cryptographic device **73** ensures that only genuine, non-expired, safe, and authenticated electrode patches **15** are permitted to provide monitoring data to a monitor recorder **14**, such as

described in commonly-assigned U.S. Pat. No. 9,655,538, issued May 23, 2017, the disclosure which is incorporated by reference.

In a further embodiment, the circuitry **70** of the electrode patch **15** includes a wireless transceiver **75**, in lieu the including of the wireless transceiver **69** in the circuitry **60** of the monitor recorder **14**, which interfaces with the microcontroller **61** over the microcontroller's expansion port via the external connector **74**.

The monitor recorder **14** continuously monitors the patient's heart rate and physiology. FIG. **11** is a flow diagram showing a monitor recorder-implemented method **100** for monitoring ECG data for use in the monitor recorder **14** of FIG. **4**. Initially, upon being connected to the set of pads **34** provided with the non-conductive receptacle **25** when the monitor recorder **14** is snapped into place, the microcontroller **61** executes a power up sequence (step **101**). During the power up sequence, the voltage of the battery **71** is checked, the state of the flash memory **62** is confirmed, both in terms of operability check and available capacity, and microcontroller operation is diagnostically confirmed. In a further embodiment, an authentication procedure between the microcontroller **61** and the electrode patch **15** are also performed.

Following satisfactory completion of the power up sequence, an iterative processing loop (steps **102**-**109**) is continually executed by the microcontroller **61**. During each iteration (step **102**) of the processing loop, the ECG frontend **63** (shown in FIG. **9**) continually senses the cutaneous ECG electrical signals (step **103**) via the ECG electrodes **38**, **29** and is optimized to maintain the integrity of the P-wave. A sample of the ECG signal is read (step **104**) by the microcontroller **61** by sampling the analog ECG signal output front end **63**. FIG. **12** is a graph showing, by way of example, a typical ECG waveform **110**. The x-axis represents time in approximate units of tenths of a second. The y-axis represents cutaneous electrical signal strength in approximate units of millivolts. The P-wave **111** has a smooth, normally upward, that is, positive, waveform that indicates atrial depolarization. The QRS complex usually begins with the downward deflection of a Q wave **112**, followed by a larger upward deflection of an R-wave **113**, and terminated with a downward waveform of the S wave **114**, collectively representative of ventricular depolarization. The T wave **115** is normally a modest upward waveform, representative of ventricular depolarization, while the U wave **116**, often not directly observable, indicates the recovery period of the Purkinje conduction fibers.

Sampling of the R-to-R interval enables heart rate information derivation. For instance, the R-to-R interval represents the ventricular rate and rhythm, while the P-to-P interval represents the atrial rate and rhythm. Importantly, the PR interval is indicative of atrioventricular (AV) conduction time and abnormalities in the PR interval can reveal underlying heart disorders, thus representing another reason why the P-wave quality achievable by the extended wear ambulatory electrocardiography and physiological sensor monitor described herein is medically unique and important. The long-term observation of these ECG indicia, as provided through extended wear of the wearable monitor **12**, provides valuable insights to the patient's cardiac function and overall well-being.

Each sampled ECG signal, in quantized and digitized form, is temporarily staged in buffer (step **105**), pending compression preparatory to storage in the flash memory **62** (step **106**). Following compression, the compressed ECG digitized sample is again buffered (step **107**), then written to

the flash memory **62** (step **108**) using the communications bus. Processing continues (step **109**), so long as the monitoring recorder **14** remains connected to the electrode patch **15** (and storage space remains available in the flash memory **62**), after which the processing loop is exited and execution terminates. Still other operations and steps are possible.

In a further embodiment, the monitor recorder **14** also continuously receives data from wearable physiology and activity sensors **131** and wearable or mobile communications devices **133** (shown in FIG. **3**). The data is received in a conceptually-separate execution thread as part of the iterative processing loop (steps **102**-**109**) continually executed by the microcontroller **61**. During each iteration (step **102**) of the processing loop, if wireless data is available (step **140**), a sample of the wireless is read (step **141**) by the microcontroller **61** and, if necessary, converted into a digital signal by the onboard ADC of the microcontroller **61**. Each wireless data sample, in quantized and digitized form, is temporarily staged in buffer (step **142**), pending compression preparatory to storage in the flash memory **62** (step **143**). Following compression, the compressed wireless data sample is again buffered (step **144**), then written to the flash memory **62** (step **145**) using the communications bus. Processing continues (step **109**), so long as the monitoring recorder **14** remains connected to the electrode patch **15** (and storage space remains available in the flash memory **62**), after which the processing loop is exited and execution terminates. Still other operations and steps are possible.

The monitor recorder **14** stores ECG data and other information in the flash memory **62** (shown in FIG. **9**) using a proprietary format that includes data compression. As a result, data retrieved from a monitor recorder **14** must first be converted into a format suitable for use by third party post-monitoring analysis software. FIG. **13** is a flow diagram showing a method **150** for offloading and converting ECG and other physiological data from an extended wear electrocardiography and physiological sensor monitor **12** in accordance with one embodiment. The method **150** can be implemented in software and execution of the software can be performed on a download station **125**, which could be a programmer or other device, or a computer system, including a server **122** or personal computer **129**, such as further described supra with reference to FIG. **3**, as a series of process or method modules or steps. For convenience, the method **150** will be described in the context of being performed by a personal computer **136** or other connectable computing device (shown in FIG. **3**) as middleware that converts ECG data and other information into a format suitable for use by a third-party post-monitoring analysis program. Execution of the method **150** by a computer system would be analogous mutatis mutandis.

Initially, the download station **125** is connected to the monitor recorder **14** (step **151**), such as by physically interfacing to a set of terminals **128** on a paired receptacle **127** or by wireless connection, if available. The data stored on the monitor recorder **14**, including ECG and physiological monitoring data, other recorded data, and other information are retrieved (step **152**) over a hard link **135** using a control program **137** ("Ctl") or analogous application executing on a personal computer **136** or other connectable computing device.

The data retrieved from the monitor recorder **14** is in a proprietary storage format and each datum of recorded ECG monitoring data, as well as any other physiological data or other information, must be converted, so that the data can be used by a third-party post-monitoring analysis program. Each datum of ECG monitoring data is converted by the

middleware (steps **153**-**159**) in an iterative processing loop. During each iteration (step **153**), the ECG datum is read (step **154**) and, if necessary, the gain of the ECG signal is adjusted (step **155**) to compensate, for instance, for relocation or replacement of the electrode patch **15** during the monitoring period.

In addition, depending upon the configuration of the wearable monitor **12**, other physiological data (or other information), including patient events, such as a fall, peak activity level, sleep detection, Detection of patient activity levels and states, and so on, may be recorded along with the ECG monitoring data. For instance, actigraphy data may have been sampled by the actigraphy sensor **64** based on a sensed event occurrence, such as a sudden change in orientation due to the patient taking a fall. In response, the monitor recorder **14** will embed the actigraphy data samples into the stream of data, including ECG monitoring data, that is recorded to the flash memory **62** by the micro-controller **61**. Post-monitoring, the actigraphy data is temporally matched to the ECG data to provide the proper physiological context to the sensed event occurrence. As a result, the three-axis actigraphy signal is turned into an actionable event occurrence that is provided, through conversion by the middleware, to third party post-monitoring analysis programs, along with the ECG recordings contemporaneous to the event occurrence. Other types of processing of the other physiological data (or other information) are possible.

Thus, during execution of the middleware, any other physiological data (or other information) that has been embedded into the recorded ECG monitoring data is read (step **156**) and time-correlated to the time frame of the ECG signals that occurred at the time that the other physiological data (or other information) was noted (step **157**). Finally, the ECG datum, signal gain adjusted, if appropriate, and other physiological data, if applicable and as time-correlated, are stored in a format suitable to the backend software (step **158**) used in post-monitoring analysis.

In a further embodiment, the other physiological data, if apropos, is embedded within an unused ECG track. For example, the SCP-ENG standard allows multiple ECG channels to be recorded into a single ECG record. The monitor recorder **14**, though, only senses one ECG channel. The other physiological data can be stored into an additional ECG channel, which would otherwise be zero-padded or altogether omitted. The backend software would then be able to read the other physiological data in context with the single channel of ECG monitoring data recorded by the monitor recorder **14**, provided the backend software implemented changes necessary to interpret the other physiological data. Still other forms of embedding of the other physiological data with formatted ECG monitoring data, or of providing the other physiological data in a separate manner, are possible.

Processing continues (step **159**) for each remaining ECG datum, after which the processing loop is exited and execution terminates. Still other operations and steps are possible.

While the invention has been particularly shown and described as referenced to the embodiments thereof, those skilled in the art will understand that the foregoing and other changes in form and detail may be made therein without departing from the spirit and scope.

What is claimed is:

1. A wearable electrocardiography monitoring device, comprising:

a flexible backing including a strip comprising:

a first face and a second face, wherein a portion of the first face is covered in adhesive to adhere the strip to skin of a patient,

a first end section,

a second end section opposite the first end section, and

a mid-section between the first end section and the second end section, wherein the mid-section is narrower than the first end section and the second end section;

a flexible circuit mounted to the second face of the strip, the flexible circuit comprising a first circuit trace and a second circuit trace;

a first electrocardiographic electrode and a second electrocardiographic electrode, wherein the first electrocardiographic electrode and the second electrocardiographic electrode are configured to sense electrocardiographic signals, wherein the first electrocardiographic electrode and the second electrocardiographic electrode are coupled to the flexible circuit, wherein the first electrocardiographic electrode is conductively exposed at the first face along the first end section of the strip, wherein the second electrocardiographic electrode is conductively exposed at the first face along the second end section of the strip, wherein the first circuit trace is electrically coupled to the first electrocardiographic electrode, wherein the second circuit trace is electrically coupled to the second electrocardiographic electrode, and wherein the first electrocardiographic electrode includes an inline resistor;

a battery vertically aligned with a sealed housing, wherein the sealed housing includes rounded edges on a top surface, wherein the sealed housing is coupled to the flexible backing, and wherein the sealed housing includes a processor, wherein the processor is electrically coupled to the first electrocardiographic electrode, the second electrocardiographic electrode, and the battery, wherein the processor is configured to process the electrocardiographic signals sensed via the first electrocardiographic electrode and the second electrocardiographic electrode; and

a wireless transceiver, wherein the wireless transceiver draws power from the battery.

2. The wearable electrocardiography monitoring device of claim **1**, wherein the mid-section comprises a first edge parallel to a second edge.

3. The wearable electrocardiography monitoring device of claim **1**, wherein the wireless transceiver is configured to communicate with an external device via Wi-Fi, mobile phone communication standards, or Bluetooth.

4. The wearable electrocardiography monitoring device of claim **1**, wherein the electrocardiographic signals are converted to a different format.

5. The wearable electrocardiography monitoring device of claim **4**, wherein the electrocardiographic signals are retrieved by one of a server, a client computer, and a mobile device via the wireless transceiver after the electrocardiographic signals are converted to the different format.

6. The wearable electrocardiography monitoring device of claim **1**, wherein the adhesive covering the portion of the first face of the strip is provided on the first end section and the second end section only.

7. The wearable electrocardiography monitoring device of claim **1**, wherein the battery is vertically aligned with the wireless transceiver.

8. A wearable electrocardiography monitoring device, comprising:

a flexible backing including a strip comprising:

a first face and a second face, wherein a portion of the first face is covered in adhesive to adhere the strip to skin of a patient,

a first end section,

a second end section opposite the first end section, and

a mid-section between the first end section and the second end section, wherein the mid-section is narrower than the first end section and the second end section, and wherein the mid-section comprises a first edge parallel to a second edge;

a flexible circuit mounted to the second face of the strip, the flexible circuit comprising a first circuit trace and a second circuit trace;

a first electrocardiographic electrode and a second electrocardiographic electrode, wherein the first electrocardiographic electrode and the second electrocardiographic electrode are configured to sense electrocardiographic signals, wherein the first electrocardiographic electrode and the second electrocardiographic electrode are coupled to the flexible circuit, wherein the first electrocardiographic electrode is conductively exposed at the first face along the first end section of the strip, wherein the second electrocardiographic electrode is conductively exposed at the first face along the second end section of the strip, wherein the first circuit trace is electrically coupled to the first electrocardiographic electrode, wherein the second circuit trace is electrically coupled to the second electrocardiographic electrode, and wherein the first electrocardiographic electrode includes an inline resistor;

a battery;

a wireless transceiver, wherein the wireless transceiver draws power from the battery; and

a sealed housing having rounded edges on a top surface, wherein the sealed housing is coupled to the flexible backing, and wherein the sealed housing includes a processor, wherein the processor is electrically coupled to the first electrocardiographic electrode, the second electrocardiographic electrode, and the battery, wherein the processor is configured to process the electrocardiographic signals sensed via the first electrocardiographic electrode and the second electrocardiographic electrode.

9. The wearable electrocardiography monitoring device of claim **8**, wherein the battery is vertically aligned with the sealed housing.

10. The wearable electrocardiography monitoring device of claim **8**, wherein the wireless transceiver is configured to communicate with an external device via Wi-Fi, mobile phone communication standards, or Bluetooth.

11. The wearable electrocardiography monitoring device of claim **8**, wherein the electrocardiographic signals are converted to a different format.

12. The wearable electrocardiography monitoring device of claim **11**, wherein the electrocardiographic signals are retrieved by one of a server, a client computer, and a mobile device via the wireless transceiver after the electrocardiographic signals are converted to the different format.

13. The wearable electrocardiography monitoring device of claim **8**, wherein the adhesive covering the portion of the first face of the strip is provided on the first end section and the second end section only.

14. The wearable electrocardiography monitoring device of claim **8**, wherein the battery is vertically aligned with the wireless transceiver.

15. A wearable electrocardiography monitoring device, comprising:

a flexible backing including a strip comprising:

a first face and a second face, wherein a portion of the first face is covered in adhesive to adhere the strip to skin of a patient,

a first end section,

a second end section opposite the first end section, and

a mid-section between the first end section and the second end section, wherein the mid-section is narrower than the first end section and the second end section, and wherein the mid-section comprises a first edge parallel to a second edge;

a flexible circuit mounted to the second face of the strip, the flexible circuit comprising a first circuit trace and a second circuit trace;

a first electrocardiographic electrode and a second electrocardiographic electrode, wherein the first electrocardiographic electrode and the second electrocardiographic electrode are configured to sense electrocardiographic signals, wherein the first electrocardiographic electrode and the second electrocardiographic electrode are coupled to the flexible circuit, wherein the first electrocardiographic electrode is conductively exposed at the first face along the first end section of the strip, wherein the second electrocardiographic electrode is conductively exposed at the first face along the second end section of the strip, wherein the first circuit trace is electrically coupled to the first electrocardiographic electrode, wherein the second circuit trace is electrically coupled to the second electrocardiographic electrode, and wherein the first electrocardiographic electrode includes an inline resistor;

a battery vertically aligned with a sealed housing, wherein the sealed housing includes rounded edges on a top surface, wherein the sealed housing is coupled to the flexible backing, and wherein the sealed housing includes a processor, wherein the processor is electrically coupled to the first electrocardiographic electrode, the second electrocardiographic electrode, and the battery, wherein the processor is configured to process the electrocardiographic signals sensed via the first electrocardiographic electrode and the second electrocardiographic electrode; and

a wireless transceiver, wherein the wireless transceiver draws power from the battery.

16. The wearable electrocardiography monitoring device of claim **15**, wherein the wireless transceiver is configured to communicate with an external device via Wi-Fi, mobile phone communication standards, or Bluetooth.

17. The wearable electrocardiography monitoring device of claim **15**, wherein the electrocardiographic signals are converted to a different format.

18. The wearable electrocardiography monitoring device of claim **17**, wherein the electrocardiographic signals are retrieved by one of a server, a client computer, and a mobile device via the wireless transceiver after the electrocardiographic signals are converted to the different format.

19. The wearable electrocardiography monitoring device of claim **15**, wherein the adhesive covering the portion of the first face of the strip is provided on the first end section and the second end section only.

20. The wearable electrocardiography monitoring device of claim **15**, wherein the battery is vertically aligned with the wireless transceiver.

21. The wearable electrocardiography monitoring device of claim **20**,

wherein the wireless transceiver is configured to communicate with an external device via Wi-Fi, mobile phone communication standards, or Bluetooth,

wherein the electrocardiographic signals are converted to a different format,

wherein the electrocardiographic signals are retrieved by one of a server, a client computer, and a mobile device via the wireless transceiver after the electrocardiographic signals are converted to the different format,

wherein the adhesive covering the portion of the first face of the strip is provided on the first end section and the second end section only, and

wherein the battery is vertically aligned with the wireless transceiver.

22. The wearable electrocardiography monitoring device of claim **20**,

wherein the wireless transceiver is configured to communicate with an external device via Wi-Fi, mobile phone communication standards, or Bluetooth,

wherein the electrocardiographic signals are retrieved by one of a server, a client computer, and a mobile device via the wireless transceiver after the electrocardiographic signals are converted to a different format,

wherein the adhesive covering the portion of the first face of the strip is provided on the first end section and the second end section only, and

wherein the battery is vertically aligned with the wireless transceiver.

23. The wearable electrocardiography monitoring device of claim **20**,

wherein the wireless transceiver is configured to communicate with an external device via Wi-Fi, mobile phone communication standards, or Bluetooth,

wherein the electrocardiographic signals are converted to a different format,

wherein the adhesive covering the portion of the first face of the strip is provided on the first end section and the second end section only, and

wherein the battery is vertically aligned with the wireless transceiver.

24. The wearable electrocardiography monitoring device of claim **20**,

wherein the wireless transceiver is configured to communicate with an external device via Wi-Fi, mobile phone communication standards, or Bluetooth,

wherein the electrocardiographic signals are converted to a different format,

wherein the electrocardiographic signals are retrieved by one of a server, a client computer, and a mobile device via the wireless transceiver after the electrocardiographic signals are converted to the different format, and

wherein the battery is vertically aligned with the wireless transceiver.

25. The wearable electrocardiography monitoring device of claim **20**,

wherein the wireless transceiver is configured to communicate with an external device via Wi-Fi, mobile phone communication standards, or Bluetooth,

wherein the electrocardiographic signals are converted to a different format,

wherein the electrocardiographic signals are retrieved by one of a server, a client computer, and a mobile device via the wireless transceiver after the electrocardiographic signals are converted to the different format, and

wherein the adhesive covering the portion of the first face of the strip is provided on the first end section and the second end section only.

26. The wearable electrocardiography monitoring device of claim **20**,

wherein the wireless transceiver is configured to communicate with an external device via Wi-Fi, mobile phone communication standards, or Bluetooth,

wherein the electrocardiographic signals are converted to a different format, and

wherein the electrocardiographic signals are retrieved by one of a server, a client computer, and a mobile device via the wireless transceiver after the electrocardiographic signals are converted to the different format.

27. The wearable electrocardiography monitoring device of claim **20**,

wherein the wireless transceiver is configured to communicate with an external device via Wi-Fi, mobile phone communication standards, or Bluetooth,

wherein the electrocardiographic signals are converted to a different format, and

wherein the adhesive covering the portion of the first face of the strip is provided on the first end section and the second end section only.

28. The wearable electrocardiography monitoring device of claim **20**,

wherein the wireless transceiver is configured to communicate with an external device via Wi-Fi, mobile phone communication standards, or Bluetooth,

wherein the electrocardiographic signals are converted to a different format, and

wherein the battery is vertically aligned with the wireless transceiver.

29. The wearable electrocardiography monitoring device of claim **20**,

wherein the wireless transceiver is configured to communicate with an external device via Wi-Fi, mobile phone communication standards, or Bluetooth,

wherein the electrocardiographic signals are retrieved by one of a server, a client computer, and a mobile device via the wireless transceiver after the electrocardiographic signals are converted to a different format, and

wherein the adhesive covering the portion of the first face of the strip is provided on the first end section and the second end section only.

30. The wearable electrocardiography monitoring device of claim **20**,

wherein the wireless transceiver is configured to communicate with an external device via Wi-Fi, mobile phone communication standards, or Bluetooth,

wherein the electrocardiographic signals are retrieved by one of a server, a client computer, and a mobile device via the wireless transceiver after the electrocardiographic signals are converted to a different format, and

wherein the battery is vertically aligned with the wireless transceiver.

* * * * *

Exhibit 2

US012171562B1

(12) **United States Patent**
Felix et al.

(10) **Patent No.: US 12,171,562 B1**
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(54) **ELECTROCARDIOGRAMY PATCH**

(71) Applicant: **Bardy Diagnostics, Inc.**, Bellevue, WA (US)

(72) Inventors: **Jason Felix**, Vashon Island, WA (US); **Jon Mikalson Bishay**, Seattle, WA (US); **Gust H. Bardy**, Carnation, WA (US)

(73) Assignee: **Bardy Diagnostics, Inc.**, Bellevue, WA (US)

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This patent is subject to a terminal disclaimer.

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A61B 5/00 (2006.01)
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CPC .... ***A61B 5/335*** (2021.01); ***A61B 5/0006*** (2013.01); ***A61B 5/0022*** (2013.01); (Continued)

(58) **Field of Classification Search**
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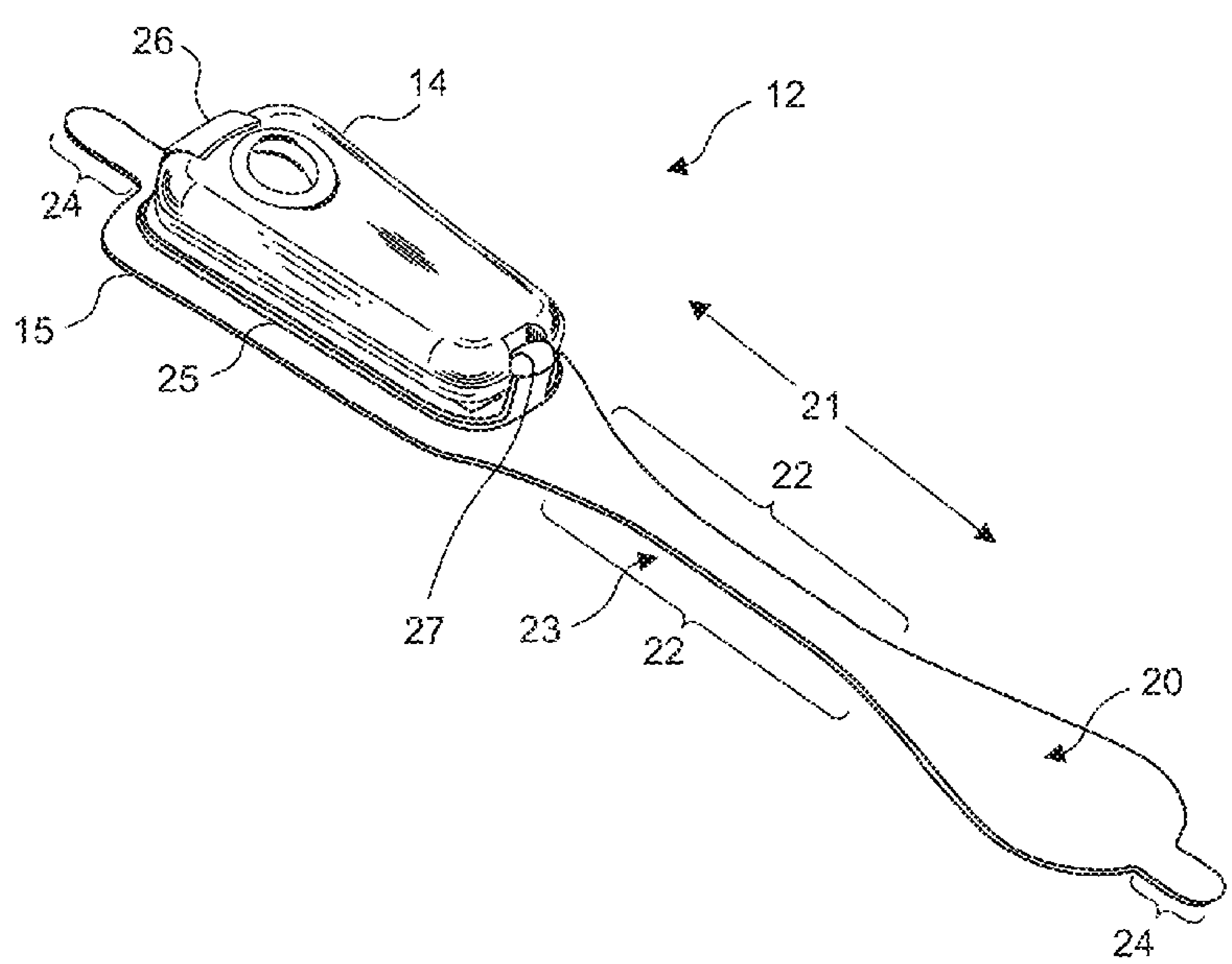
Primary Examiner — George Manuel
(74) *Attorney, Agent, or Firm* — K&L Gates LLP

(57) **ABSTRACT**

An apparatus is provided. A strip has first and second end sections, and a first face and second face. Two electrocardiographic electrodes are provided on the strip with one of the electrocardiographic electrodes provided on the first face of the first end section of the strip and another of the electrocardiographic electrodes positioned on the first face on the second end section of the strip. A flexible circuit is mounted to the second face of the strip and includes a circuit trace electrically coupled to each of the electrocardiographic electrodes. The apparatus includes a wireless transceiver and a battery.

30 Claims, 8 Drawing Sheets



Related U.S. Application Data

continuation of application No. 18/353,398, filed on Jul. 17, 2023, which is a continuation of application No. 17/946,933, filed on Sep. 16, 2022, now Pat. No. 11,723,575, which is a continuation of application No. 17/367,476, filed on Jul. 5, 2021, now Pat. No. 11,445,967, which is a continuation of application No. 17/119,945, filed on Dec. 11, 2020, now Pat. No. 11,051,743, which is a continuation of application No. 16/241,929, filed on Jan. 7, 2019, now Pat. No. 10,888,239, which is a continuation of application No. 15/818,437, filed on Nov. 20, 2017, now Pat. No. 10,172,534, which is a continuation of application No. 15/256,266, filed on Sep. 2, 2016, now Pat. No. 9,820,665, which is a continuation of application No. 14/082,071, filed on Nov. 15, 2013, now Pat. No. 9,433,367, which is a continuation-in-part of application No. 14/080,717, filed on Nov. 14, 2013, now Pat. No. 9,545,204, and a continuation-in-part of application No. 14/080,725, filed on Nov. 14, 2013, now Pat. No. 9,730,593.

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A61B 5/03	(2006.01)
A61B 5/08	(2006.01)
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A61B 5/11	(2006.01)
A61B 5/1455	(2006.01)
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CPC A61B 5/021; A61B 5/03; A61B 5/0816; A61B 5/087; A61B 5/1118; A61B 5/14532; A61B 5/14542; A61B 5/14551; A61B 5/259; A61B 5/282; A61B 5/335; A61B 5/349; A61B 5/6823; A61B 5/6833; A61B 5/7405; A61B 5/7455; A61B 5/7475; G16H 40/63; G16H 40/67

See application file for complete search history.

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Chart A-3 Invalidity Contentions: U.S. Pat. No. 11,051,743; Case No. 22-351-CJB (Delaware); Invalidity of U.S. Pat. No. 11,051,743 by U.S. Pat. No. 10,327,660 ("Gallego"); Oct. 25, 2023; 12 pages.
Chart A-3 Invalidity Contentions: U.S. Pat. No. 11,445,967; Case No. 22-351-CJB (Delaware); Invalidity of U.S. Pat. No. 11,445,967 by U.S. Pat. No. 10,327,660 ("Gallego"); Oct. 25, 2023; 7 pages.
Chart A-4 Invalidity Contentions: U.S. Pat. No. 11,051,743; Case No. 22-351-CJB (Delaware); Invalidity of U.S. Pat. No. 11,051,743 by U.S. Pat. Pub. No. 2011/0077497 ("Oster"); Oct. 25, 2023; 11 pages.
Chart A-4 Invalidity Contentions: U.S. Pat. No. 11,445,967; Case No. 22-351-CJB (Delaware); Invalidity of U.S. Pat. No. 11,445,967 by U.S. Pat. Pub. No. 2011/0077497 ("Oster"); Oct. 25, 2023; 6 pages.
Chart A-5 Invalidity Contentions: U.S. Pat. No. 11,051,743; Case No. 22-351-CJB (Delaware); Invalidity of U.S. Pat. No. 11,051,743 by U.S. Pat. No. 10,413,251 ("Golda"); Oct. 25, 2023; 11 pages.
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Chart AA-9 Invalidity Contentions: U.S. Pat. No. 11,445,967; Case No. 22-351-CJB (Delaware); Invalidity of U.S. Pat. No. 11,445,967 by U.S. Pat. Pub. No. 2011/0009729 ("Shin"); Oct. 25, 2023; 6 pages.
Chart AA-10 Invalidity Contentions: U.S. Pat. No. 11,445,967; Case No. 22-351-CJB (Delaware); Invalidity of U.S. Pat. No. 11,445,967 by WO 2003/065926 ("Ozguz"); Oct. 25, 2023; 6 pages.
Chart B-1 Invalidity Contentions: U.S. Pat. No. 11,051,743 and U.S. Pat. No. 11,445,967; Case No. 22-351-CJB (Delaware); Elongated Strip With Narrowed Midsection; Oct. 25, 2023; 8 pages.
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Chart B-3 Invalidity Contentions: U.S. Pat. No. 11,051,743 and U.S. Pat. No. 11,445,967; Case No. 22-351-CJB (Delaware); Flexible Circuit Comprising a Pair of Circuit Traces to Couple Electrodes; Oct. 25, 2023; 8 pages.
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Fig. 1.

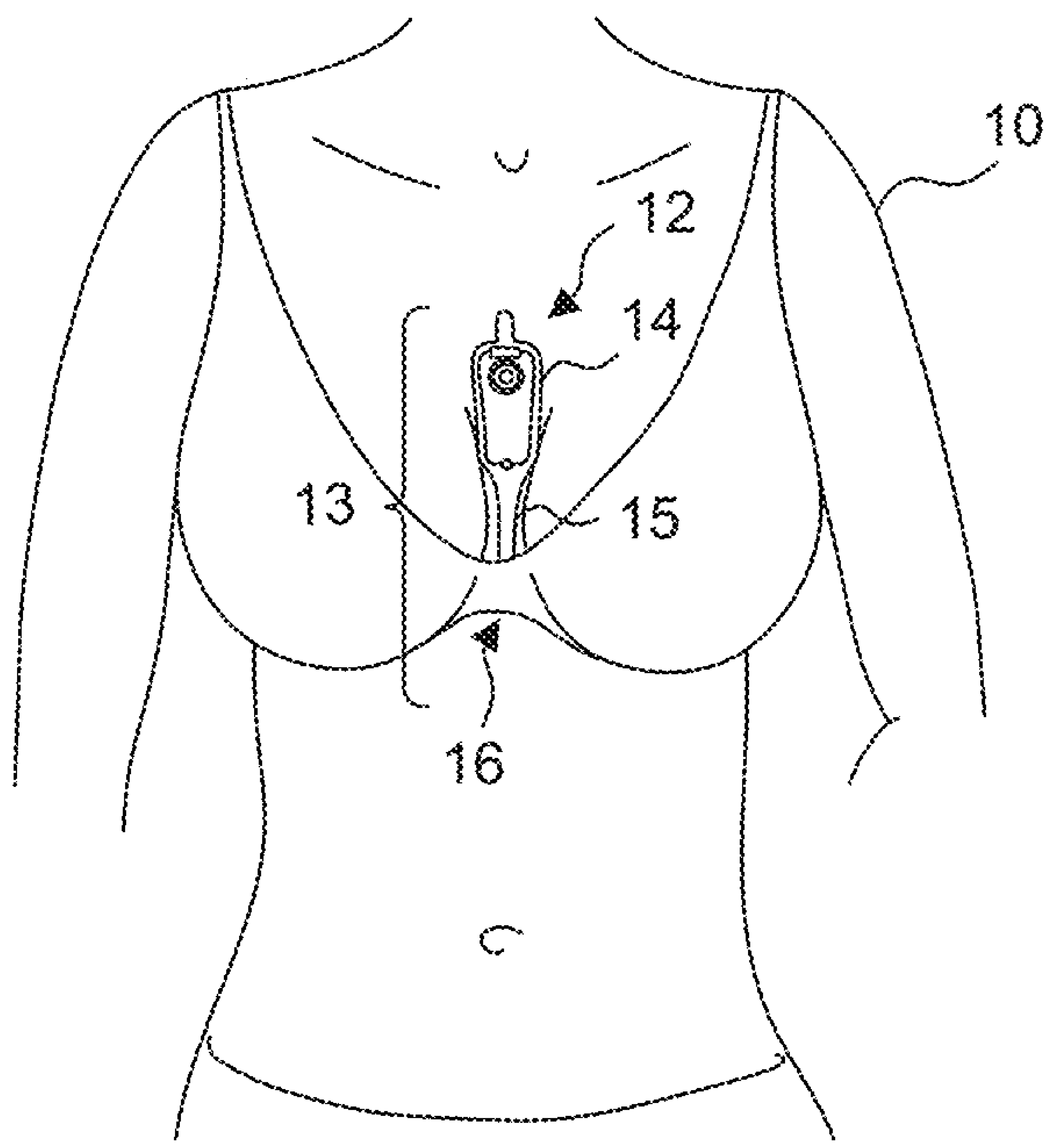


Fig. 2.

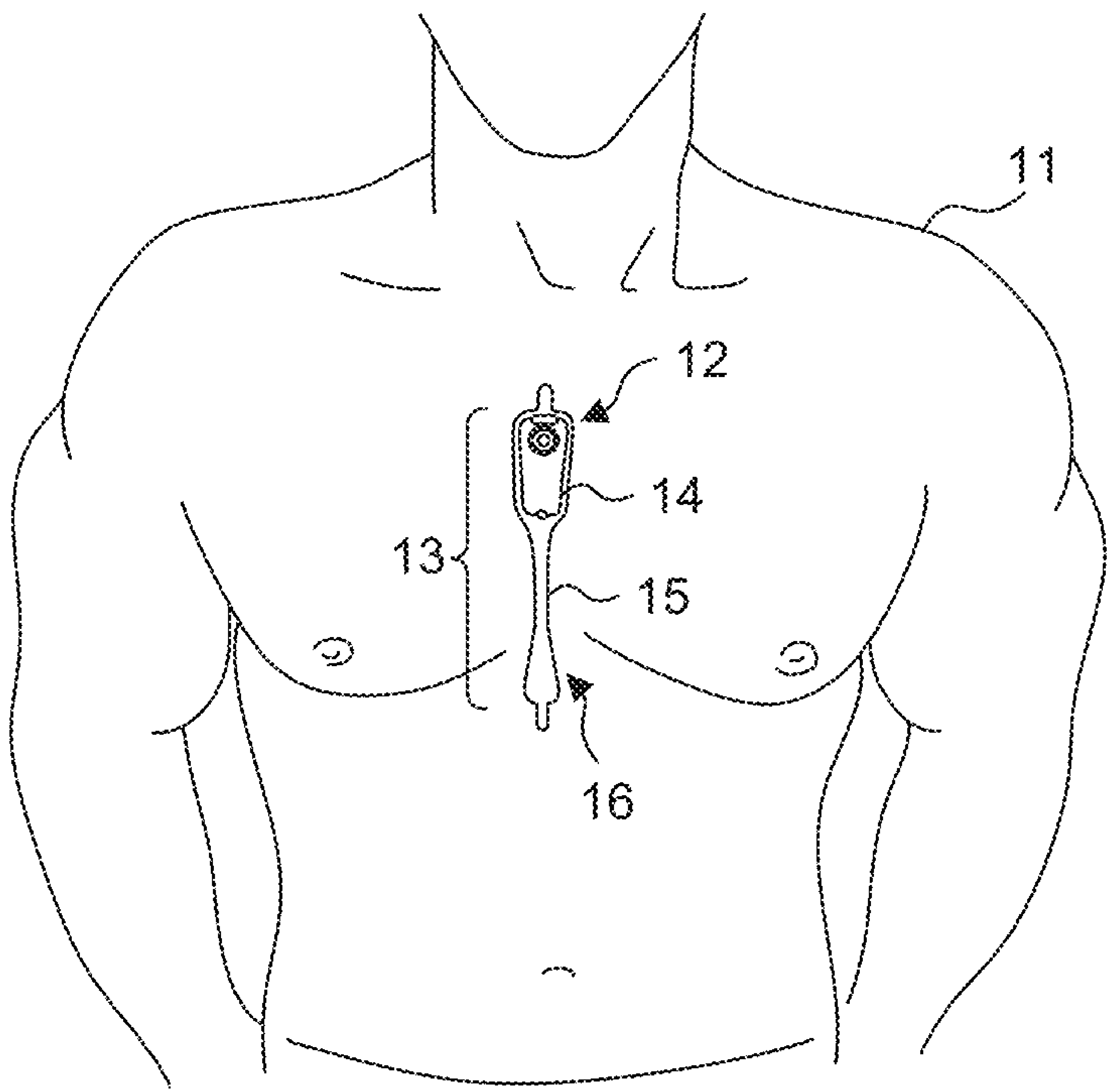


Fig. 3.

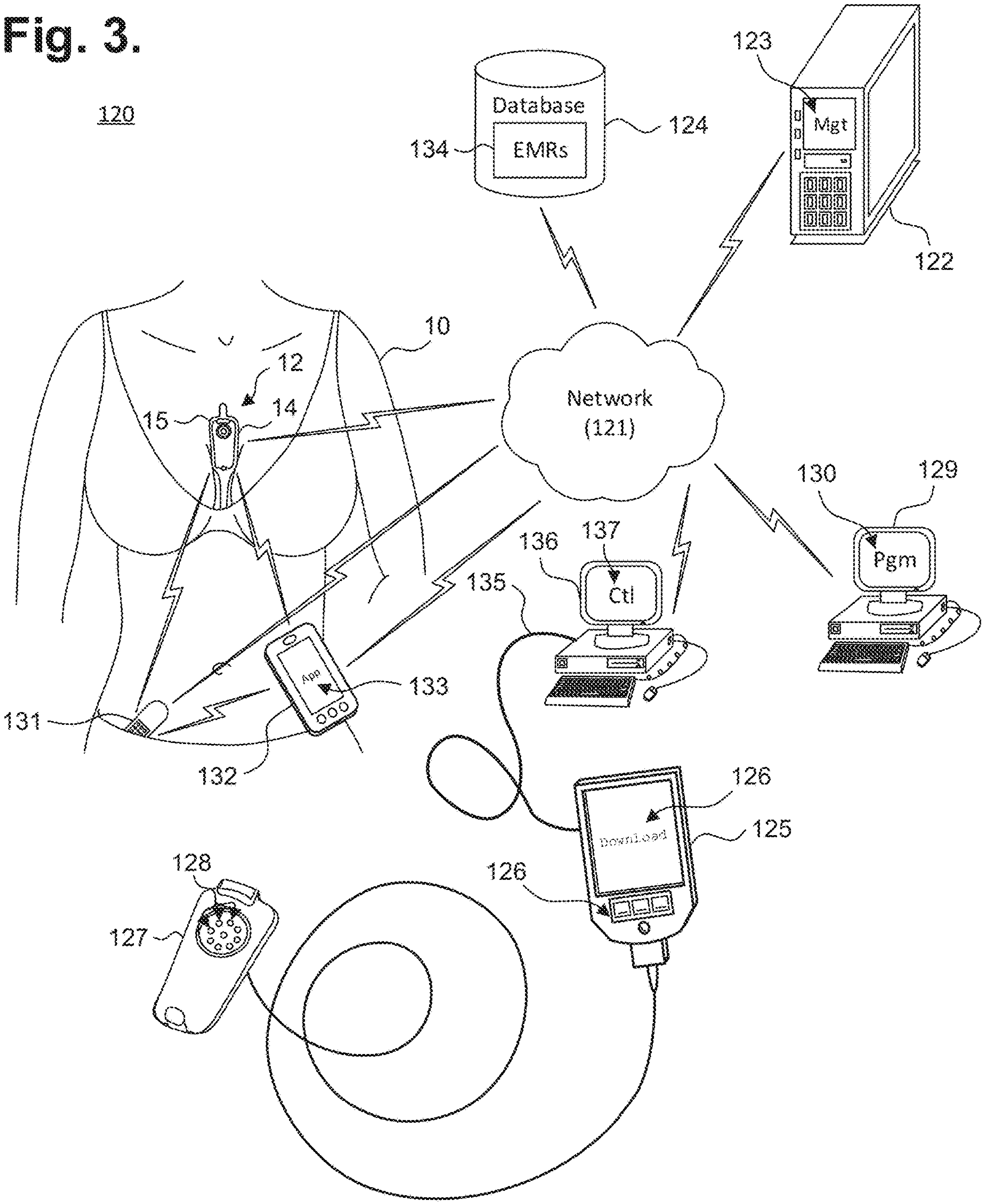

120
Database
EMRs
134
124
123
Mgt
122
10
12
14
15
Network
(121)
130
129
Pgm
136
137
Ctl
135
133
App
131
132
126
125
Download
126
128
127

Fig. 4.

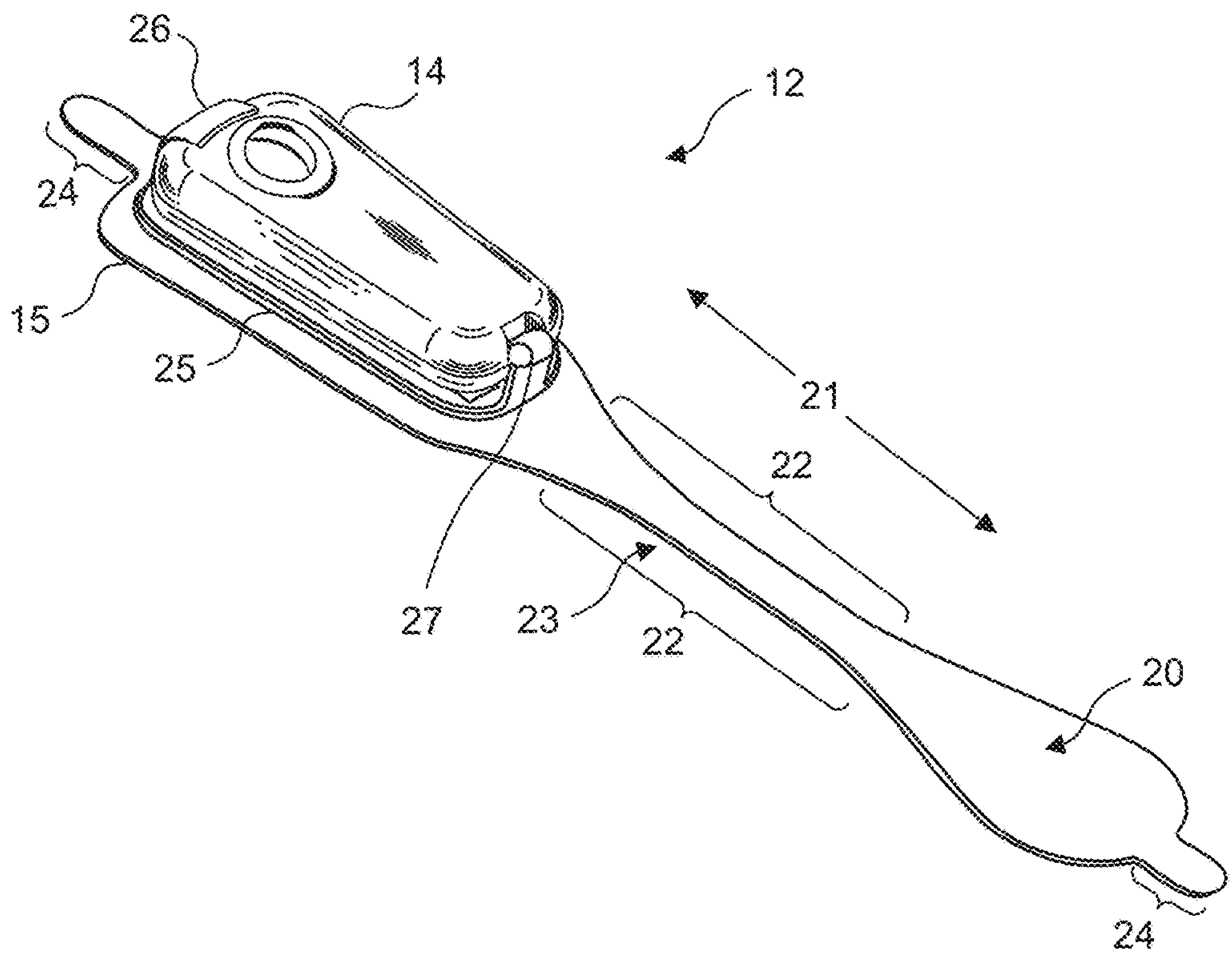


Fig. 5.

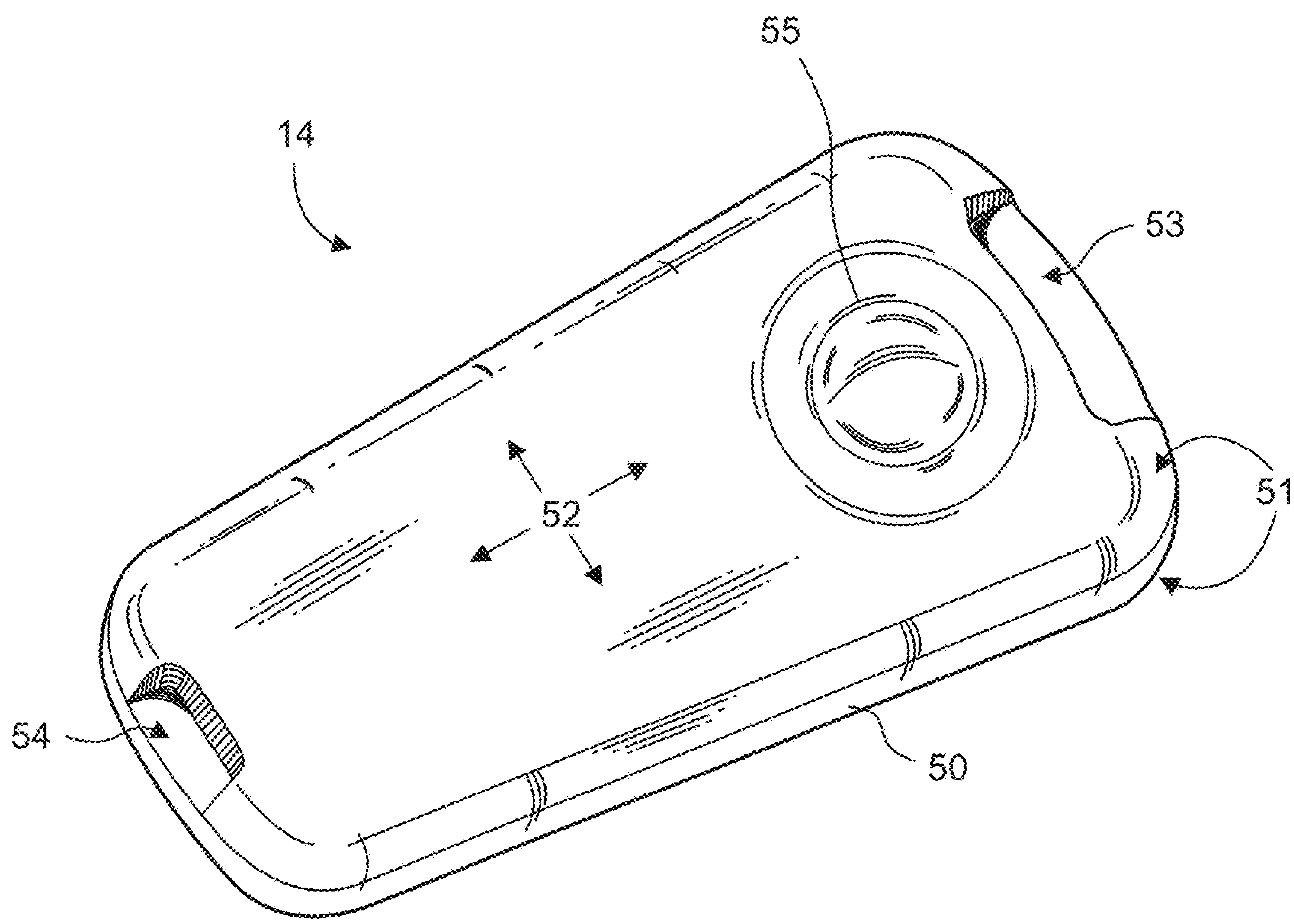


Fig. 6.

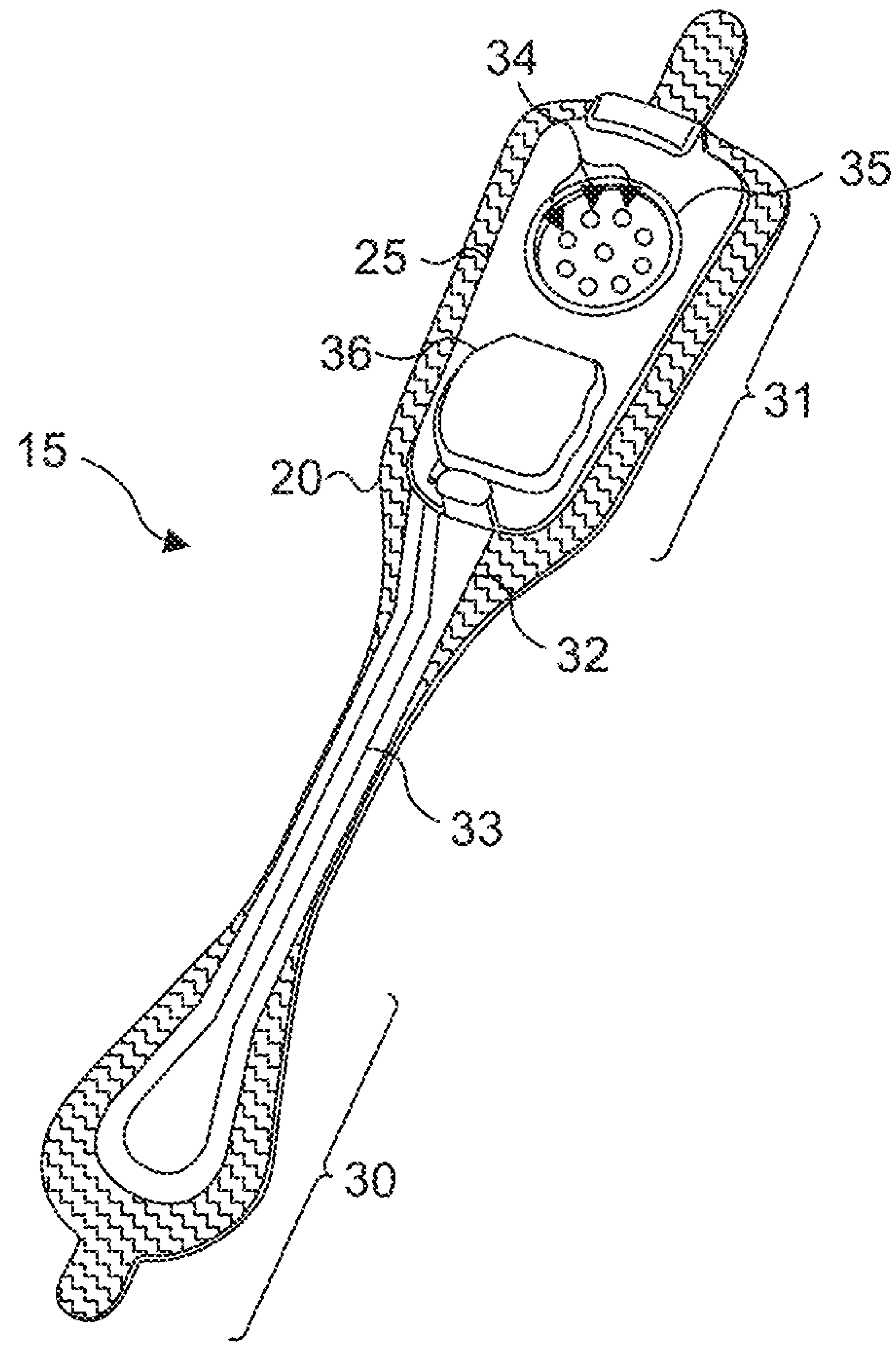


Fig. 7.

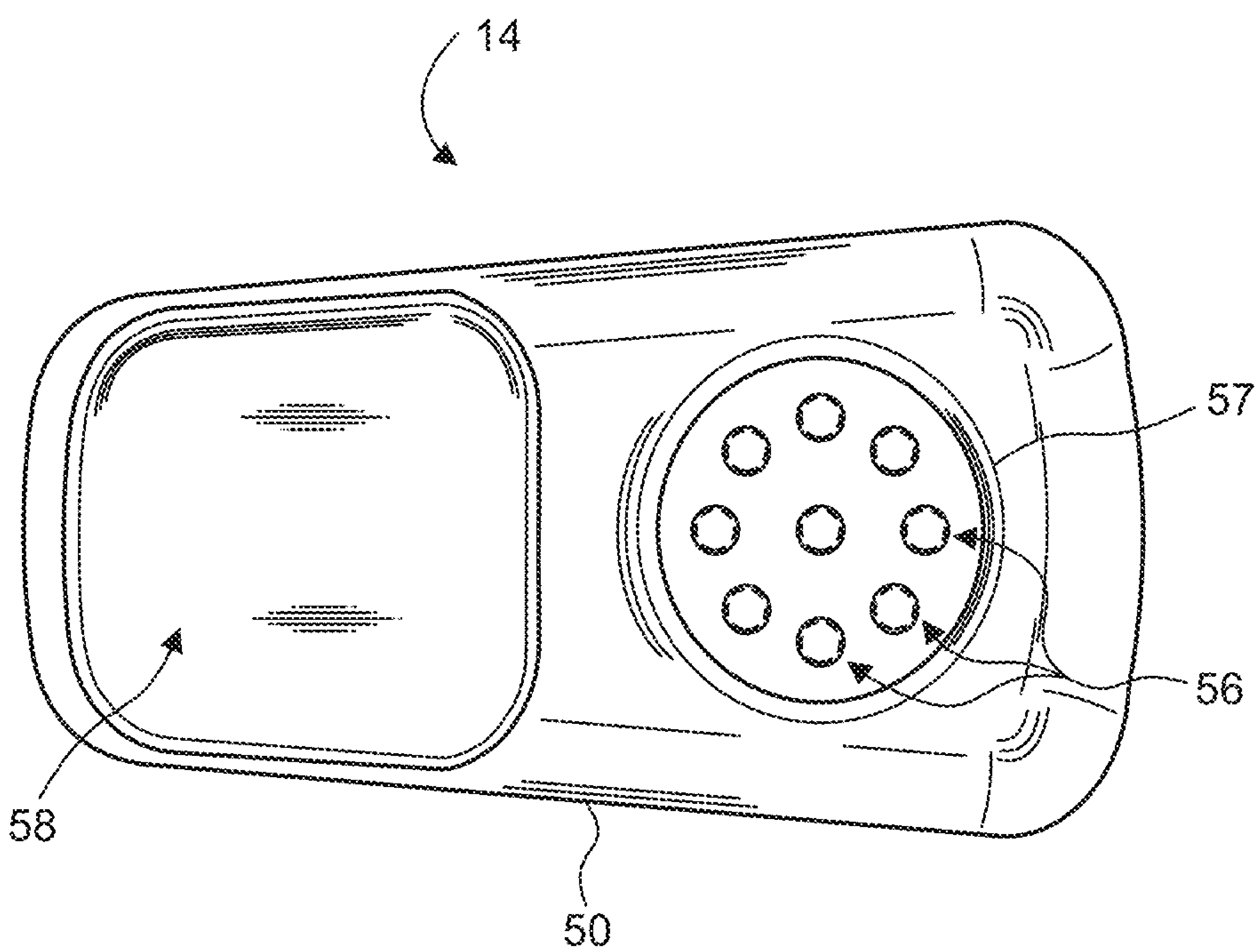


Fig. 8.

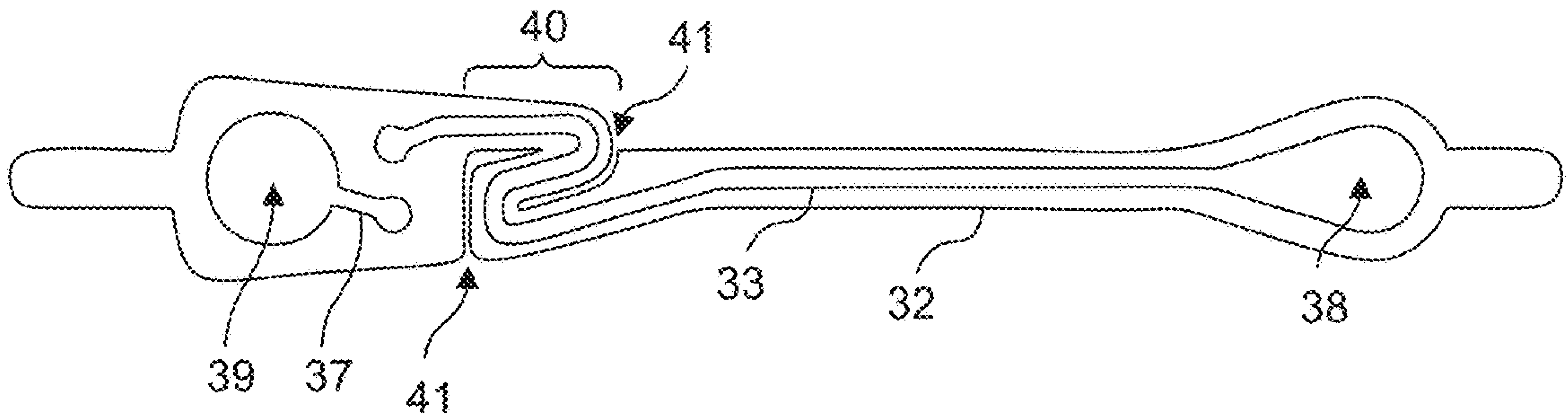


Fig. 9.

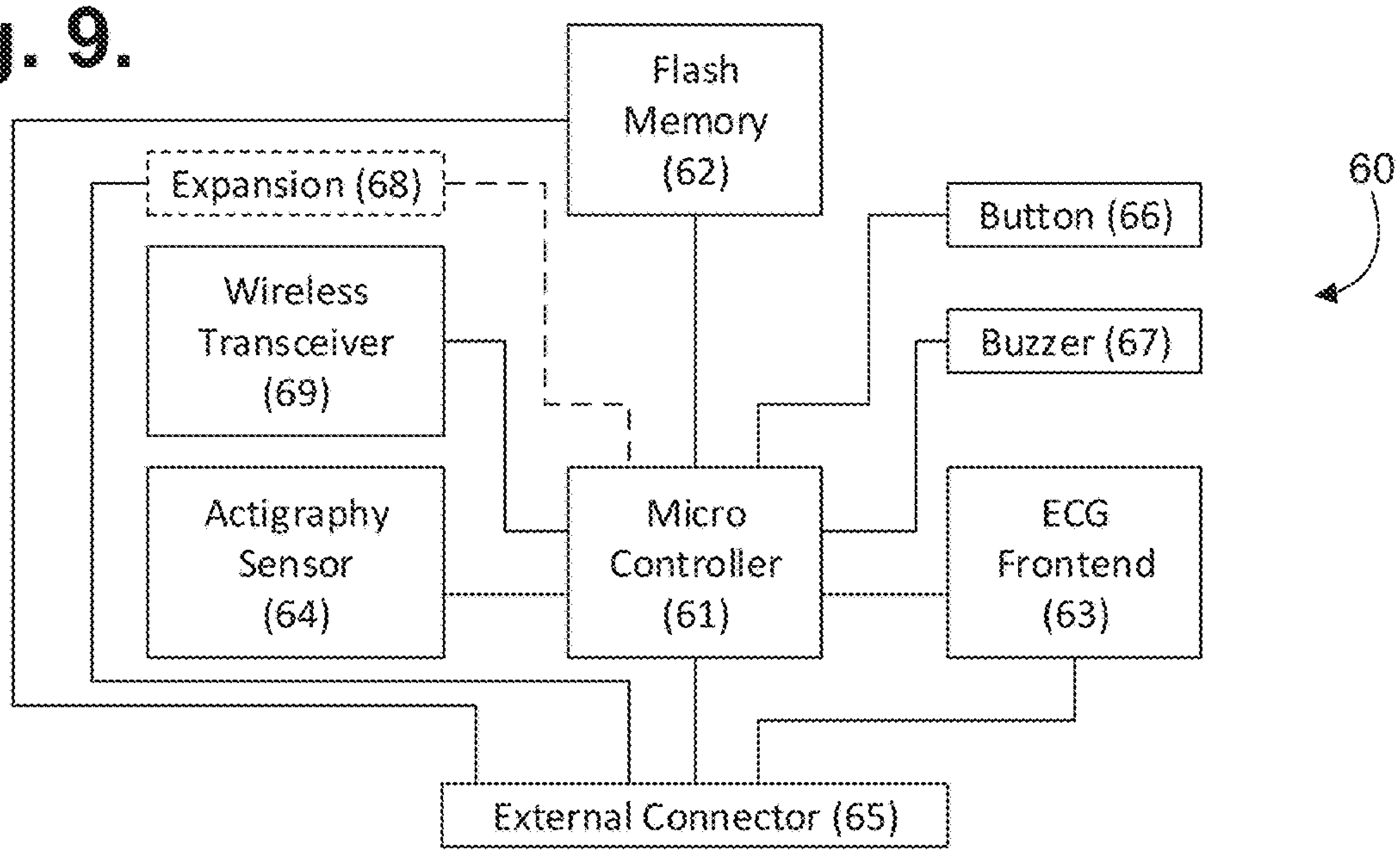


Fig. 10.

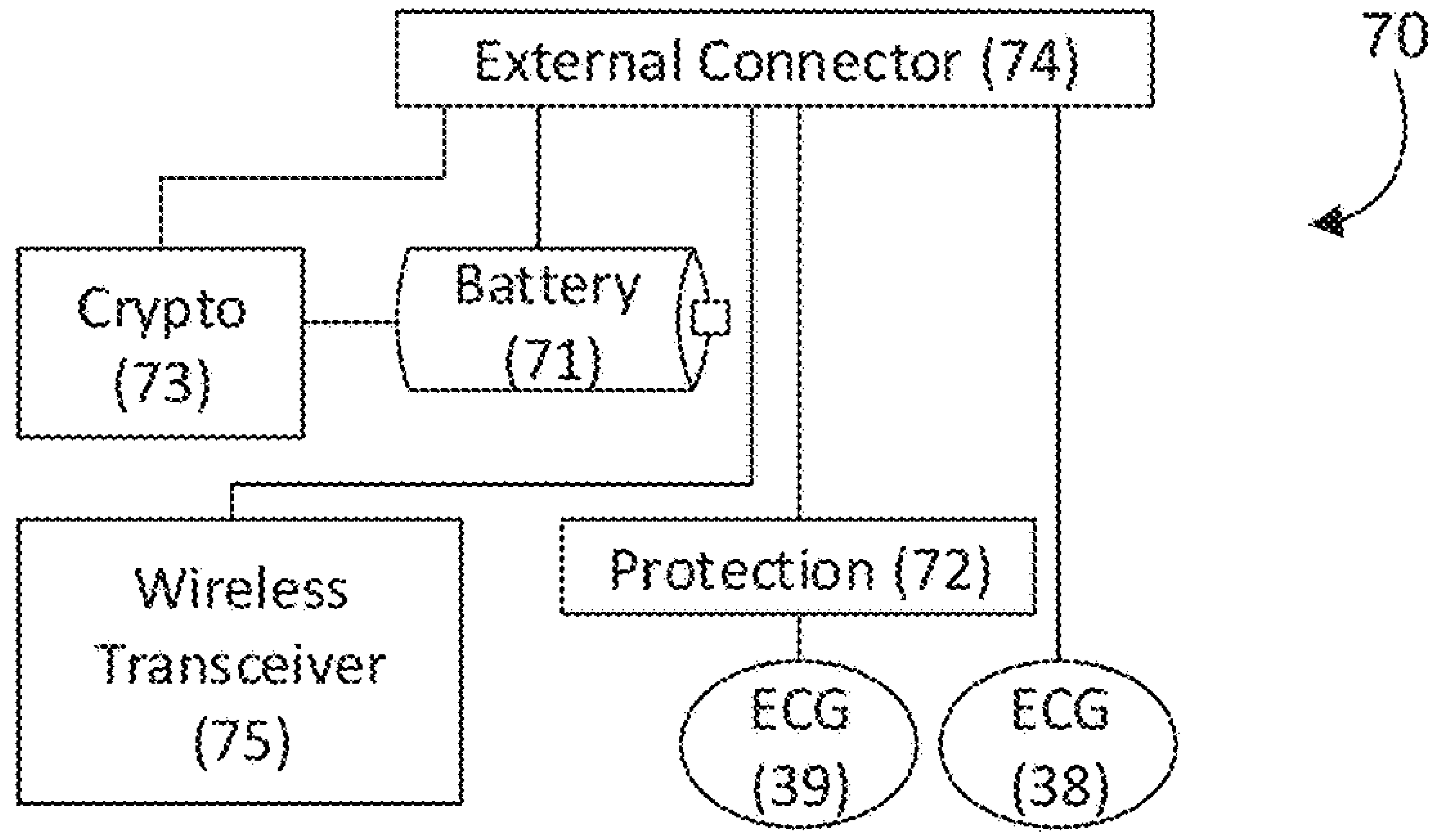


Fig. 11.

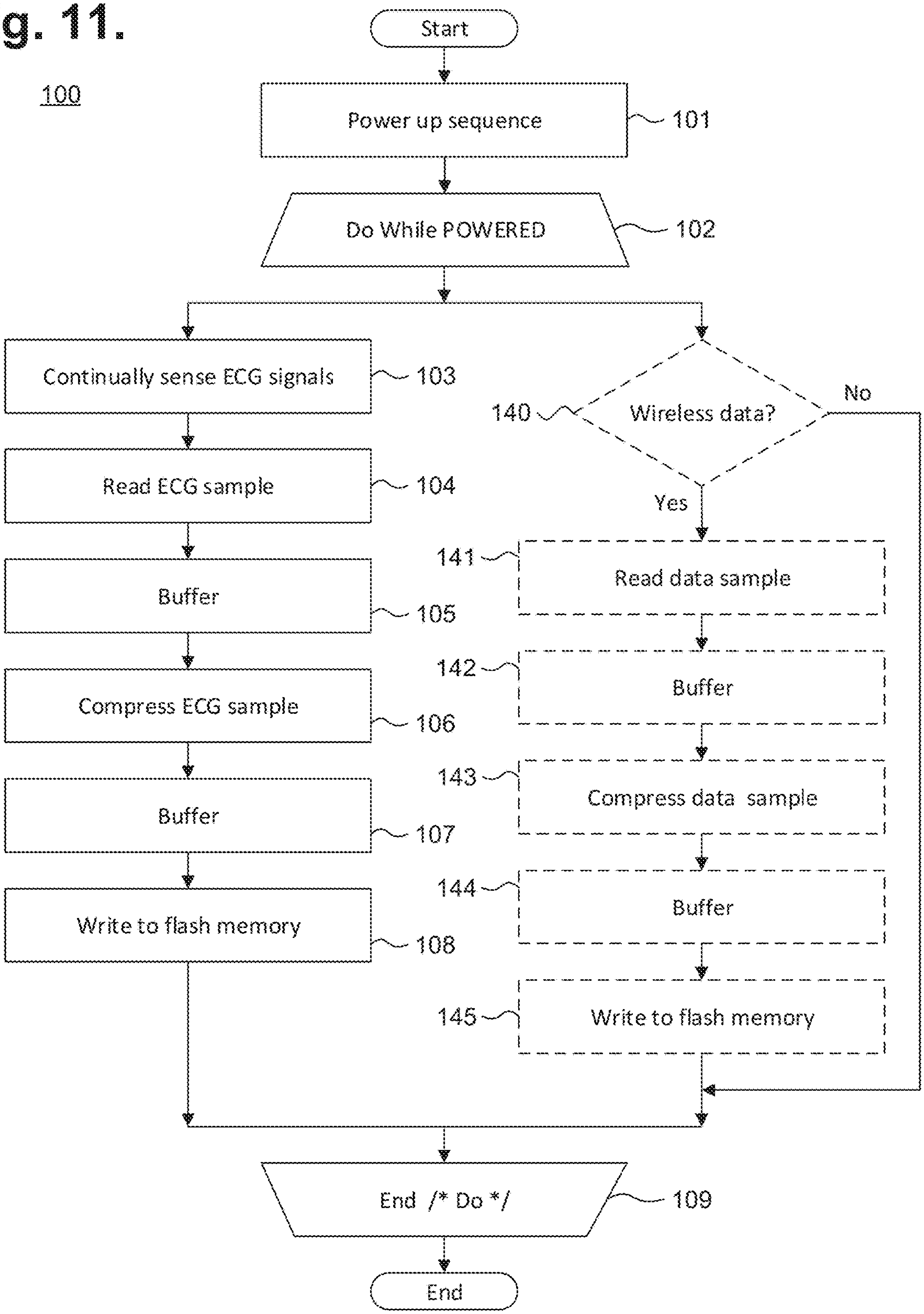

100
Start
Power up sequence
101
Do While POWERED
102
Continually sense ECG signals
103
Read ECG sample
104
Buffer
105
Compress ECG sample
106
Buffer
107
Write to flash memory
108
140
Wireless data?
No
Yes
141
Read data sample
142
Buffer
143
Compress data sample
144
Buffer
145
Write to flash memory
End /* Do */
109
End

Fig. 12.

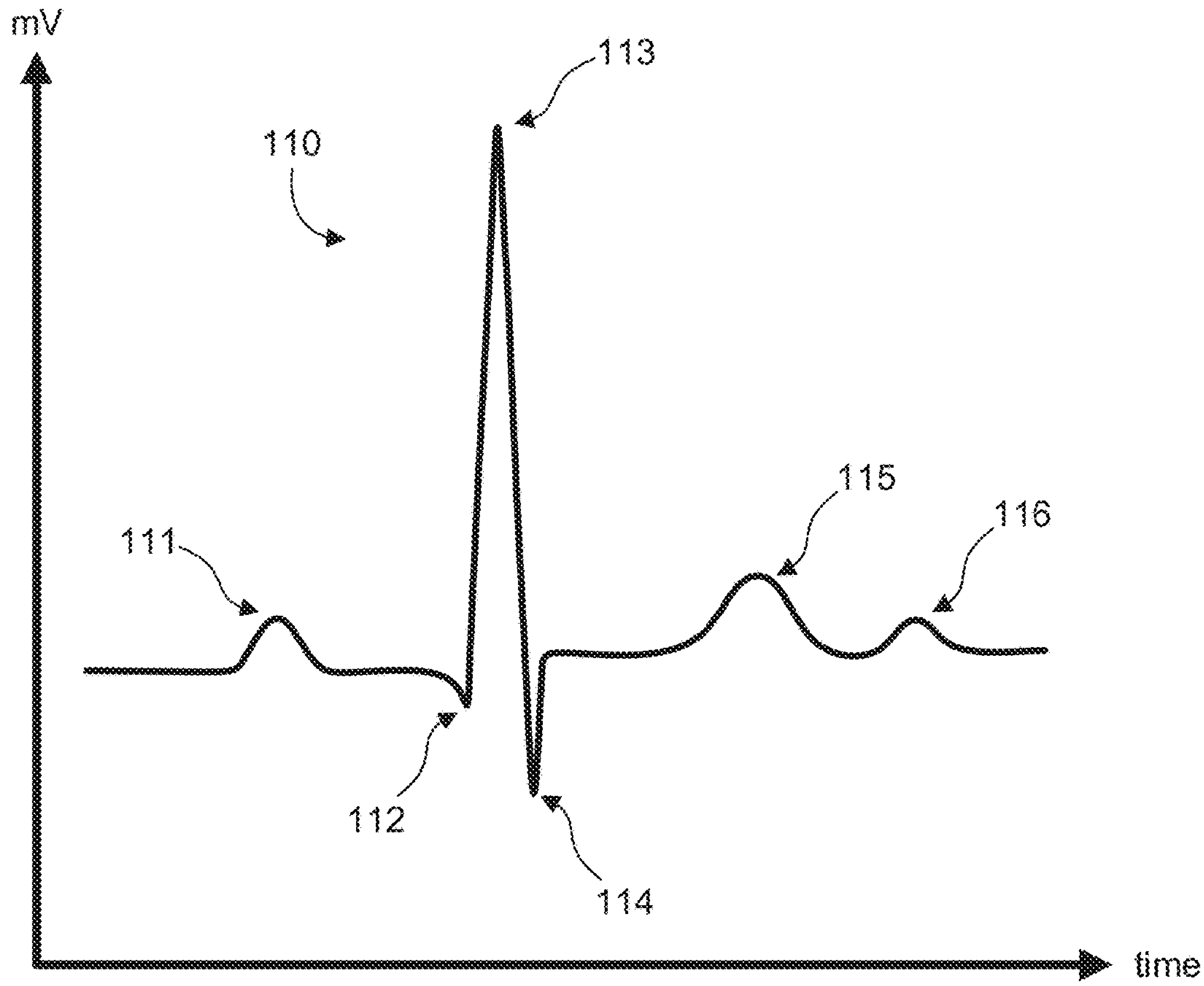
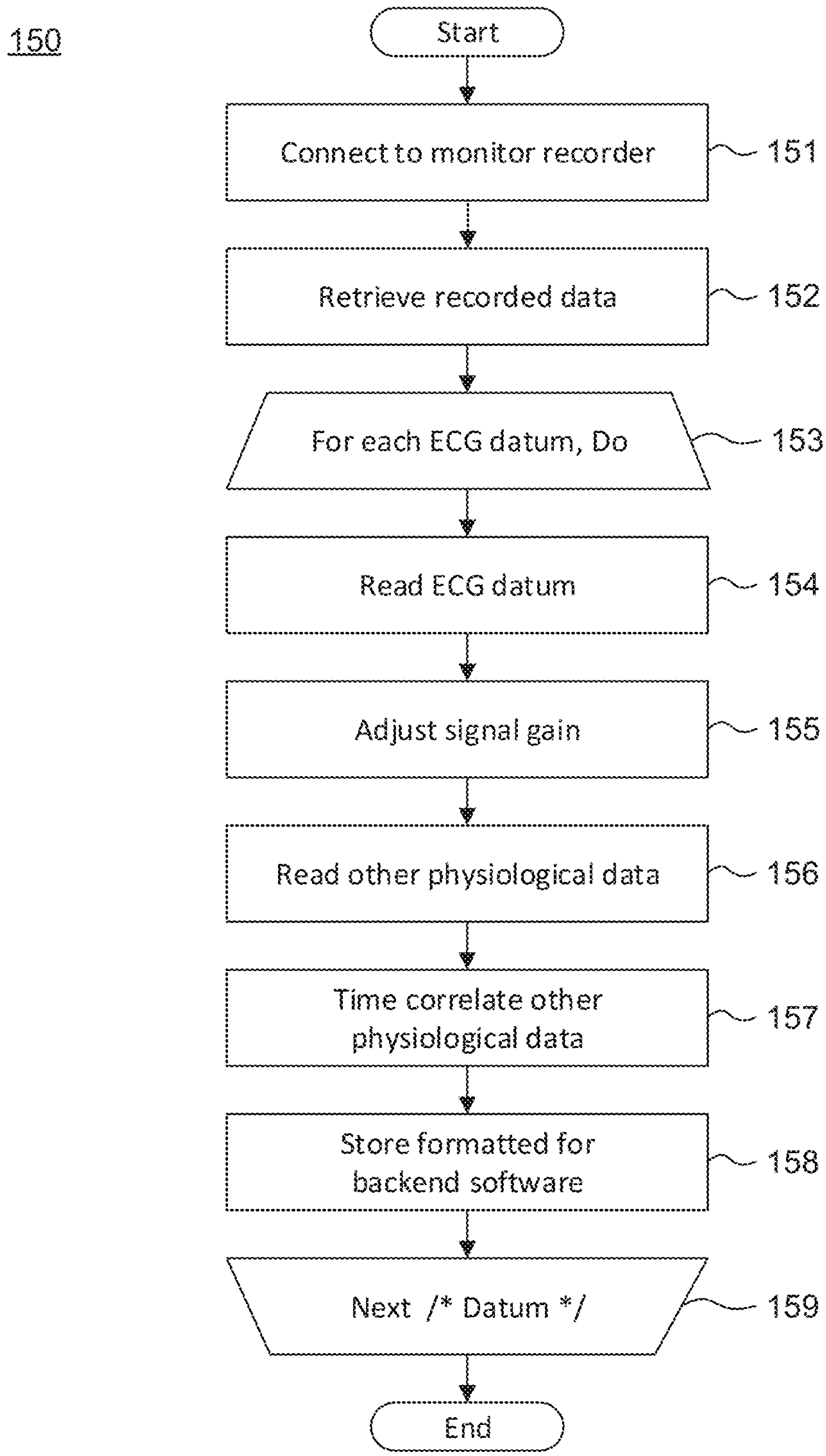


Fig. 13.


150
Start
Connect to monitor recorder
151
Retrieve recorded data
152
For each ECG datum, Do
153
Read ECG datum
154
Adjust signal gain
155
Read other physiological data
156
Time correlate other physiological data
157
Store formatted for backend software
158
Next /* Datum */
159
End

ELECTROCARDIOGRAMY PATCH

PRIORITY CLAIM AND CROSS-REFERENCE TO RELATED APPLICATIONS

This application is a continuation of U.S. patent application Ser. No. 18/647,762, filed Apr. 26, 2024, titled ELECTROCARDIOGRAPHY PATCH, which is a continuation of U.S. patent application Ser. No. 18/353,398, filed Jul. 17, 2023, titled ELECTROCARDIOGRAPHY PATCH, which is a continuation of U.S. patent application Ser. No. 17/946,933, filed Sep. 16, 2022, titled ELECTROCARDIOGRAPHY PATCH, which is a continuation of U.S. patent application Ser. No. 17/367,476, filed Jul. 5, 2021, titled ELECTROCARDIOGRAPHY PATCH, which is a continuation of U.S. patent application Ser. No. 17/119,945, filed Dec. 11, 2020, titled ELECTROCARDIOGRAPHY PATCH, which is a continuation of U.S. patent application Ser. No. 16/241,929, filed Jan. 7, 2019, titled REMOTE INTERFACING ELECTROCARDIOGRAPHY PATCH, which is a continuation of U.S. patent application Ser. No. 15/818,437, filed Nov. 20, 2017, titled REMOTE INTERFACING ELECTROCARDIOGRAPHY PATCH, which is a continuation of U.S. patent application Ser. No. 15/256,266, filed Sep. 2, 2016, titled REMOTE INTERFACING OF EXTENDED WEAR ELECTROCARDIOGRAPHY AND PHYSIOLOGICAL SENSOR MONITOR, which is a continuation of U.S. patent application Ser. No. 14/082,071, filed Nov. 15, 2013, titled REMOTE INTERFACING OF EXTENDED WEAR ELECTROCARDIOGRAPHY AND PHYSIOLOGICAL SENSOR MONITOR, which is a continuation-in-part of U.S. patent application Ser. No. 14/080,717, filed Nov. 14, 2013, titled EXTENDED WEAR ELECTROCARDIOGRAPHY PATCH, which claims priority to U.S. Provisional Patent App. No. 61/882,403, filed Sep. 25, 2013, titled LONG-TERM WEARABLE PHYSIOLOGICAL MONITOR. U.S. patent application Ser. No. 14/082,071 is also a continuation-in-part of U.S. patent application Ser. No. 14/080,725, filed Nov. 14, 2013, titled EXTENDED WEAR AMBULATORY ELECTROCARDIOGRAPHY AND PHYSIOLOGICAL SENSOR MONITOR, which claims priority to U.S. Provisional Patent App. No. 61/882,403, filed Sep. 25, 2013, titled LONG-TERM WEARABLE PHYSIOLOGICAL MONITOR. The entire contents of these applications are incorporated by reference herein in their entirely and relied upon.

FIELD

This application relates in general to electrocardiographic monitoring and, in particular, to an electrocardiography patch.

BACKGROUND

The heart emits electrical signals as a by-product of the propagation of the action potentials that trigger depolarization of heart fibers. An electrocardiogram (ECG) measures and records such electrical potentials to visually depict the electrical activity of the heart over time. Conventionally, a standardized set format 12-lead configuration is used by an ECG machine to record cardiac electrical signals from well-established traditional chest locations. Electrodes at the end of each lead are placed on the skin over the anterior thoracic region of the patient's body to the lower right and to the lower left of the sternum, on the left anterior chest, and on the limbs. Sensed cardiac electrical activity is represented

by PQRSTU waveforms that can be interpreted post-ECG recordation to derive heart rate and physiology. The P-wave represents atrial electrical activity. The QRSTU components represent ventricular electrical activity.

An ECG is a tool used by physicians to diagnose heart problems and other potential health concerns. An ECG is a snapshot of heart function, typically recorded over 12 seconds, that can help diagnose rate and regularity of heartbeats, effect of drugs or cardiac devices, including pacemakers and implantable cardioverter-defibrillators (ICDs), and whether a patient has heart disease. ECGs are used in-clinic during appointments, and, as a result, are limited to recording only those heart-related aspects present at the time of recording. Sporadic conditions that may not show up during a spot ECG recording require other means to diagnose them. These disorders include fainting or syncope; rhythm disorders, such as tachyarrhythmias and bradyarrhythmias; apneic episodes; and other cardiac and related disorders. Thus, an ECG only provides a partial picture and can be insufficient for complete patient diagnosis of many cardiac disorders.

Diagnostic efficacy can be improved, when appropriate, through the use of long-term extended ECG monitoring. Recording sufficient ECG and related physiology over an extended period is challenging, and often essential to enabling a physician to identify events of potential concern. A 30-day observation period is considered the "gold standard" of ECG monitoring, yet achieving a 30-day observation day period has proven unworkable because such ECG monitoring systems are arduous to employ, cumbersome to the patient, and excessively costly. Ambulatory monitoring in-clinic is implausible and impracticable. Nevertheless, if a patient's ECG could be recorded in an ambulatory setting, thereby allowing the patient to engage in activities of daily living, the chances of acquiring meaningful information and capturing an abnormal event while the patient is engaged in normal activities becomes more likely to be achieved.

For instance, the long-term wear of ECG electrodes is complicated by skin irritation and the inability ECG electrodes to maintain continual skin contact after a day or two. Moreover, time, dirt, moisture, and other environmental contaminants, as well as perspiration, skin oil, and dead skin cells from the patient's body, can get between an ECG electrode, the non-conductive adhesive used to adhere the ECG electrode, and the skin's surface. All of these factors adversely affect electrode adhesion and the quality of cardiac signal recordings. Furthermore, the physical movements of the patient and their clothing impart various compressional, tensile, and torsional forces on the contact point of an ECG electrode, especially over long recording times, and an inflexibly fastened ECG electrode will be prone to becoming dislodged. Moreover, dislodgment may occur unbeknownst to the patient, making the ECG recordings worthless. Further, some patients may have skin that is susceptible to itching or irritation, and the wearing of ECG electrodes can aggravate such skin conditions. Thus, a patient may want or need to periodically remove or replace ECG electrodes during a long-term ECG monitoring period, whether to replace a dislodged electrode, reestablish better adhesion, alleviate itching or irritation, allow for cleansing of the skin, allow for showering and exercise, or for other purpose. Such replacement or slight alteration in electrode location actually facilitates the goal of recording the ECG signal for long periods of time.

Conventionally, Holter monitors are widely used for long-term extended ECG monitoring. Typically, they are used for only 24-48 hours. A typical Holter monitor is a wearable and

portable version of an ECG that include cables for each electrode placed on the skin and a separate battery-powered ECG recorder. The cable and electrode combination (or leads) are placed in the anterior thoracic region in a manner similar to what is done with an in-clinic standard ECG machine. The duration of a Holter monitoring recording depends on the sensing and storage capabilities of the monitor, as well as battery life. A "looping" Holter monitor (or event) can operate for a longer period of time by overwriting older ECG tracings, thence "recycling" storage in favor of extended operation, yet at the risk of losing event data. Although capable of extended ECG monitoring, Holter monitors are cumbersome, expensive and typically only available by medical prescription, which limits their usability. Further, the skill required to properly place the electrodes on the patient's chest hinders or precludes a patient from replacing or removing the precordial leads and usually involves moving the patient from the physician office to a specialized center within the hospital or clinic.

The ZIO XT Patch and ZIO Event Card devices, manufactured by iRhythm Tech., Inc., San Francisco, CA, are wearable stick-on monitoring devices that are typically worn on the upper left pectoral region to respectively provide continuous and looping ECG recording. The location is used to simulate surgically implanted monitors. Both of these devices are prescription-only and for single patient use. The ZIO XT Patch device is limited to a 14-day monitoring period, while the electrodes only of the ZIO Event Card device can be worn for up to 30 days. The ZIO XT Patch device combines both electronic recordation components, including battery, and physical electrodes into a unitary assembly that adheres to the patient's skin. The ZIO XT Patch device uses adhesive sufficiently strong to support the weight of both the monitor and the electrodes over an extended period of time and to resist disadherance from the patient's body, albeit at the cost of disallowing removal or relocation during the monitoring period. Moreover, throughout monitoring, the battery is continually depleted and battery capacity can potentially limit overall monitoring duration. The ZIO Event Card device is a form of downsized Holter monitor with a recorder component that must be removed temporarily during baths or other activities that could damage the non-waterproof electronics. Both devices represent compromises between length of wear and quality of ECG monitoring, especially with respect to ease of long term use, female-friendly fit, and quality of atrial (P-wave) signals.

In addition, with the advent of wireless communications and wearable computing, other types of personal ambulatory monitors, of varying degrees of sophistication, have become increasingly available. For example, adherents to the so-called "Quantified Self" movement combine wearable sensors and wearable computing to self-track activities of their daily lives, including inputs, states, and performance. The Nike+ FuelBand, manufactured by Nike Inc., Beaverton, OR, for instance, provides an activity tracker that is worn on the wrist and allows the wearer to temporally track the number of foot steps taken each day and an estimation of the calories burned. The activity tracker can interface with a smart phone device to allow a wearer to monitor their progress towards a fitness goal. Such quantified physiology, however, is typically tracked for only the personal use of the wearer and is not time-correlated to physician-supervised monitoring.

Therefore, a need remains for an extended wear continuously recording ECG monitor practically capable of being worn for a long period of time in both men and women and capable of recording atrial signals reliably.

A further need remains for facilities to integrate wider-ranging physiological and "life tracking"-type data into long-term ECG and physiological data monitoring.

SUMMARY

Physiological monitoring can be provided through a wearable monitor that includes two components, a flexible extended wear electrode patch and a removable reusable monitor recorder. The wearable monitor sits centrally (in the midline) on the patient's chest along the sternum oriented top-to-bottom. The placement of the wearable monitor in a location at the sternal midline (or immediately to either side of the sternum), with its unique narrow "hourglass"-like shape, benefits long-term extended wear by removing the requirement that ECG electrodes be continually placed in the same spots on the skin throughout the monitoring period. Instead, the patient is free to place an electrode patch anywhere within the general region of the sternum, the area most likely to record high quality atrial signals or P-waves. The wearable monitor can also interoperate wirelessly with other wearable physiology and activity sensors and with wearable or mobile communications devices, including so-called "smart phones," to download monitoring data either in real-time or in batches. The monitor recorder can also be equipped with a wireless transceiver to either provide data or other information to, or receive data or other information from, an interfacing wearable physiology and activity sensor, or wearable or mobile communications devices for relay to a further device, such as a server, analysis, or other purpose.

One embodiment provides a remotely-interfaceable electrocardiography patch. The remotely-interfaceable electrocardiography patch includes a backing formed of a strip of material and an electrocardiographic electrode on each end of the backing to capture electrocardiographic signals. A flexible circuit includes a pair of circuit traces electrically coupled to the electrocardiographic electrodes. A wireless transceiver communicates at least one of the electrocardiographic signals and other physiological measures with one or more of a physiology and activity sensor, communication device, server, and personal computer.

A further embodiment provides an electrocardiography patch. The patch includes a backing and at least two electrocardiographic electrodes each positioned on the backing, across from another of the electrocardiographic electrodes, to capture electrocardiographic signals. A flexible circuit includes a pair of circuit traces electrically coupled to the electrocardiographic electrodes. A wireless transceiver communicates at least a portion of the electrocardiographic signals.

A still further embodiment provides an apparatus. A strip has first and second end sections, and a first surface and second surface. Two electrocardiographic electrodes are provided on the strip with one of the electrocardiographic electrodes provided on the first surface of the first end section of the strip and another of the electrocardiographic electrodes positioned on the first surface on the second end section of the strip. A flexible circuit is mounted to the second surface of the strip and includes a circuit trace electrically coupled to each of the electrocardiographic electrodes. A wireless transceiver is affixed on one of the first or second end sections, and a battery is positioned on one of

the first or second end sections. A processor is positioned on one of the first or second end sections and is housed separate from the battery.

The monitoring patch is especially suited to the female anatomy. The narrow longitudinal midsection can fit nicely within the intermammary cleft of the breasts without inducing discomfort, whereas conventional patch electrodes are wide and, if adhesed between the breasts, would cause chafing, irritation, frustration, and annoyance, leading to low patient compliance.

The foregoing aspects enhance ECG monitoring performance and quality, facilitating long-term ECG recording, critical to accurate arrhythmia diagnosis.

In addition, the foregoing aspects enhance comfort in women (and certain men), but not irritation of the breasts, by placing the monitoring patch in the best location possible for optimizing the recording of cardiac signals from the atrium, another feature critical to proper arrhythmia diagnosis.

Finally, the foregoing aspects as relevant to monitoring are equally applicable to recording other physiological measures, such as temperature, respiratory rate, blood sugar, oxygen saturation, and blood pressure, as well as other measures of body chemistry and physiology.

Still other embodiments will become readily apparent to those skilled in the art from the following detailed description, wherein are described embodiments by way of illustrating the best mode contemplated. As will be realized, other and different embodiments are possible and the embodiments' several details are capable of modifications in various obvious respects, all without departing from their spirit and the scope. Accordingly, the drawings and detailed description are to be regarded as illustrative in nature and not as restrictive.

BRIEF DESCRIPTION OF THE DRAWINGS

FIGS. **1** and **2** are diagrams showing, by way of examples, an extended wear electrocardiography and physiological sensor monitor respectively fitted to the sternal region of a female patient and a male patient.

FIG. **3** is a functional block diagram showing a system for remote interfacing of an extended wear electrocardiography and physiological sensor monitor in accordance with one embodiment.

FIG. **4** is a perspective view showing an extended wear electrode patch with a monitor recorder inserted.

FIG. **5** is a perspective view showing the monitor recorder of FIG. **4**.

FIG. **6** is a perspective view showing the extended wear electrode patch of FIG. **4** without a monitor recorder inserted.

FIG. **7** is a bottom plan view of the monitor recorder of FIG. **4**.

FIG. **8** is a top view showing the flexible circuit of the extended wear electrode patch of FIG. **4** when mounted above the flexible backing.

FIG. **9** is a functional block diagram showing the component architecture of the circuitry of the monitor recorder of FIG. **4**.

FIG. **10** is a functional block diagram showing the circuitry of the extended wear electrode patch of FIG. **4**.

FIG. **11** is a flow diagram showing a monitor recorder-implemented method for monitoring ECG data for use in the monitor recorder of FIG. **4**.

FIG. **12** is a graph showing, by way of example, a typical ECG waveform.

FIG. **13** is a flow diagram showing a method for offloading and converting ECG and other physiological data from an extended wear electrocardiography and physiological sensor monitor in accordance with one embodiment.

DETAILED DESCRIPTION

Physiological monitoring can be provided through a wearable monitor that includes two components, a flexible extended wear electrode patch and a removable reusable monitor recorder. FIGS. **1** and **2** are diagrams showing, by way of examples, an extended wear electrocardiography and physiological sensor monitor **12**, including a monitor recorder **14** in accordance with one embodiment, respectively fitted to the sternal region of a female patient **10** and a male patient **11**. The wearable monitor **12** sits centrally (in the midline) on the patient's chest along the sternum **13** oriented top-to-bottom with the monitor recorder **14** preferably situated towards the patient's head. In a further embodiment, the orientation of the wearable monitor **12** can be corrected post-monitoring, as further described infra. The electrode patch **15** is shaped to fit comfortably and conformal to the contours of the patient's chest approximately centered on the sternal midline **16** (or immediately to either side of the sternum **13**). The distal end of the electrode patch **15** extends towards the Xiphoid process and, depending upon the patient's build, may straddle the region over the Xiphoid process. The proximal end of the electrode patch **15**, located under the monitor recorder **14**, is below the manubrium and, depending upon patient's build, may straddle the region over the manubrium.

The placement of the wearable monitor **12** in a location at the sternal midline **16** (or immediately to either side of the sternum **13**) significantly improves the ability of the wearable monitor **12** to cutaneously sense cardiac electric signals, particularly the P-wave (or atrial activity) and, to a lesser extent, the QRS interval signals in the ECG waveforms that indicate ventricular activity, while simultaneously facilitating comfortable long-term wear for many weeks. The sternum **13** overlies the right atrium of the heart and the placement of the wearable monitor **12** in the region of the sternal midline **13** puts the ECG electrodes of the electrode patch **15** in a location better adapted to sensing and recording P-wave signals than other placement locations, say, the upper left pectoral region or lateral thoracic region or the limb leads. In addition, placing the lower or inferior pole (ECG electrode) of the electrode patch **15** over (or near) the Xiphoid process facilitates sensing of ventricular activity and provides superior recordation of the QRS interval.

When operated standalone, the monitor recorder **14** of the extended wear electrocardiography and physiological sensor monitor **12** senses and records the patient's ECG data into an onboard memory. In addition, the wearable monitor **12** can interoperate with other devices. FIG. **3** is a functional block diagram showing a system **120** for remote interfacing of an extended wear electrocardiography and physiological sensor monitor **12** in accordance with one embodiment. The monitor recorder **14** is a reusable component that can be fitted during patient monitoring into a non-conductive receptacle provided on the electrode patch **15**, as further described infra with reference to FIG. **4**, and later removed for offloading of stored ECG data or to receive revised programming. The monitor recorder **14** can then be connected to a download station **125**, which could be a programmer or other device that permits the retrieval of stored ECG monitoring data, execution of diagnostics on or programming of the monitor recorder **14**, or performance of other functions. The monitor

recorder **14** has a set of electrical contacts (not shown) that enable the monitor recorder **14** to physically interface to a set of terminals **128** on a paired receptacle **127** of the download station **125**. In turn, the download station **125** executes a communications or offload program **126** ("Offload") or similar program that interacts with the monitor recorder **14** via the physical interface to retrieve the stored ECG monitoring data. The download station **125** could be a server, personal computer, tablet or handheld computer, smart mobile device, or purpose-built programmer designed specific to the task of interfacing with a monitor recorder **14**. Still other forms of download station **125** are possible.

Upon retrieving stored ECG monitoring data from a monitor recorder **14**, middleware first operates on the retrieved data to adjust the ECG capture quality, as necessary, and to convert the retrieved data into a format suitable for use by third party post-monitoring analysis software, as further described infra with reference to FIG. **13**. The formatted data can then be retrieved from the download station **125** over a hard link **135** using a control program **137** ("Ctl") or analogous application executing on a personal computer **136** or other connectable computing device, via a communications link (not shown), whether wired or wireless, or by physical transfer of storage media (not shown). The personal computer **136** or other connectable device may also execute middleware that converts ECG data and other information into a format suitable for use by a third-party post-monitoring analysis program, as further described infra with reference to FIG. **13**. Note that formatted data stored on the personal computer **136** would have to be maintained and safeguarded in the same manner as electronic medical records (EMRs) **134** in the secure database **124**, as further discussed infra. In a further embodiment, the download station **125** is able to directly interface with other devices over a computer communications network **121**, which could be some combination of a local area network and a wide area network, including the Internet, over a wired or wireless connection.

A client-server model could be used to employ a server **122** to remotely interface with the download station **125** over the network **121** and retrieve the formatted data or other information. The server **122** executes a patient management program **123** ("Mgt") or similar application that stores the retrieved formatted data and other information in a secure database **124** cataloged in that patient's EMRs **134**. In addition, the patient management program **123** could manage a subscription service that authorizes a monitor recorder **14** to operate for a set period of time or under pre-defined operational parameters.

The patient management program **123**, or other trusted application, also maintains and safeguards the secure database **124** to limit access to patient EMRs **134** to only authorized parties for appropriate medical or other uses, such as mandated by state or federal law, such as under the Health Insurance Portability and Accountability Act (HIPAA) or per the European Union's Data Protection Directive. For example, a physician may seek to review and evaluate his patient's ECG monitoring data, as securely stored in the secure database **124**. The physician would execute an application program **130** ("Pgm"), such as a post-monitoring ECG analysis program, on a personal computer **129** or other connectable computing device, and, through the application **130**, coordinate access to his patient's EMRs **134** with the patient management program **123**. Other schemes and safeguards to protect and maintain the integrity of patient EMRs **134** are possible.

The wearable monitor **12** can interoperate wirelessly with other wearable physiology and activity sensors **131** and with wearable or mobile communications devices **133**. Wearable physiology and activity sensors **131** encompass a wide range of wirelessly interconnectable devices that measure or monitor data physical to the patient's body, such as heart rate, temperature, blood pressure, and so forth; physical states, such as movement, sleep, footsteps, and the like; and performance, including calories burned or estimated blood glucose level. These devices originate both within the medical community to sense and record traditional medical physiology that could be useful to a physician in arriving at a patient diagnosis or clinical trajectory, as well as from outside the medical community, from, for instance, sports or lifestyle product companies who seek to educate and assist individuals with self-quantifying interests.

Frequently, wearable physiology and activity sensors **131** are capable of wireless interfacing with wearable or mobile communications devices **133**, particularly smart mobile devices, including so-called "smart phones," to download monitoring data either in real-time or in batches. The wearable or mobile communications device **133** executes an application ("App") that can retrieve the data collected by the wearable physiology and activity sensor **131** and evaluate the data to generate information of interest to the wearer, such as an estimation of the effectiveness of the wearer's exercise efforts. Still other wearable or mobile communications device **133** functions on the collected data are possible.

The wearable or mobile communications devices **133** could also serve as a conduit for providing the data collected by the wearable physiology and activity sensor **131** to a server **122**, or, similarly, the wearable physiology and activity sensor **131** could itself directly provide the collected data to the server **122**. The server **122** could then merge the collected data into the wearer's EMRs **134** in the secure database **124**, if appropriate (and permissible), or the server **122** could perform an analysis of the collected data, perhaps based by comparison to a population of like wearers of the wearable physiology and activity sensor **131**. Still other server **122** functions on the collected data are possible.

Finally, the monitor recorder **14** can also be equipped with a wireless transceiver, as further described infra with reference to FIGS. **9** and **10**. Thus, when wireless-enabled, both wearable physiology and activity sensors **131** and wearable or mobile communications devices **133** could wirelessly interface with the monitor recorder **14**, which could either provide data or other information to, or receive data or other information from an interfacing device for relay to a further device, such as the server **122**, analysis, or other purpose. In addition, the monitor recorder **14** could wirelessly interface directly with the server **122**, personal computer **129**, or other computing device connectable over the network **121**, when the monitor recorder **14** is appropriately equipped for interfacing with such devices. Still other types of remote interfacing of the monitor recorder **14** are possible.

During use, the electrode patch **15** is first adhered to the skin along the sternal midline **16** (or immediately to either side of the sternum **13**). A monitor recorder **14** is then snapped into place on the electrode patch **15** to initiate ECG monitoring. FIG. **4** is a perspective view showing an extended wear electrode patch **15** with a monitor recorder **14** in accordance with one embodiment inserted. The body of the electrode patch **15** is preferably constructed using a flexible backing **20** formed as an elongated strip **21** of wrap knit or similar stretchable material with a narrow longitudinal mid-section **23** evenly tapering inward from both sides. A pair of cut-outs **22** between the distal and proximal

ends of the electrode patch **15** create a narrow longitudinal midsection **23** or "isthmus" and defines an elongated "hourglass"-like shape, when viewed from above.

The electrode patch **15** incorporates features that significantly improve wearability, performance, and patient comfort throughout an extended monitoring period. During wear, the electrode patch **15** is susceptible to pushing, pulling, and torqueing movements, including compressional and torsional forces when the patient bends forward, and tensile and torsional forces when the patient leans backwards. To counter these stress forces, the electrode patch **15** incorporates strain and crimp reliefs, such as described in commonly-assigned U.S. Patent, entitled "Extended Wear Electrocardiography Patch," U.S. Pat. No. 9,545,204, issued Jan. 17, 2017, the disclosure of which is incorporated by reference. In addition, the cut-outs **22** and longitudinal midsection **23** help minimize interference with and discomfort to breast tissue, particularly in women (and gynecomastic men). The cut-outs **22** and longitudinal midsection **23** further allow better conformity of the electrode patch **15** to sternal bowing and to the narrow isthmus of flat skin that can occur along the bottom of the intermammary cleft between the breasts, especially in buxom women. The cut-outs **22** and longitudinal midsection **23** help the electrode patch **15** fit nicely between a pair of female breasts in the intermammary cleft. Still other shapes, cut-outs and conformities to the electrode patch **15** are possible.

The monitor recorder **14** removably and reusably snaps into an electrically non-conductive receptacle **25** during use. The monitor recorder **14** contains electronic circuitry for recording and storing the patient's electrocardiography as sensed via a pair of ECG electrodes provided on the electrode patch **15**, such as described in commonly-assigned U.S. Patent, entitled "Extended Wear Ambulatory Electrocardiography and Physiological Sensor Monitor," U.S. Pat. No. 9,730,593, issued Aug. 15, 2017, the disclosure which is incorporated by reference. The non-conductive receptacle **25** is provided on the top surface of the flexible backing **20** with a retention catch **26** and tension clip **27** molded into the non-conductive receptacle **25** to conformably receive and securely hold the monitor recorder **14** in place.

The monitor recorder **14** includes a sealed housing that snaps into place in the non-conductive receptacle **25**. FIG. **5** is a perspective view showing the monitor recorder **14** of FIG. **4**. The sealed housing **50** of the monitor recorder **14** intentionally has a rounded isosceles trapezoidal-like shape **52**, when viewed from above, such as described in commonly-assigned U.S. Design Patent, entitled "Electrocardiography Monitor," No. D717,955, issued Nov. 18, 2014, the disclosure of which is incorporated by reference. The edges **51** along the top and bottom surfaces are rounded for patient comfort. The sealed housing **50** is approximately 47 mm long, 23 mm wide at the widest point, and 7 mm high, excluding a patient-operable tactile-feedback button **55**. The sealed housing **50** can be molded out of polycarbonate, ABS, or an alloy of those two materials. The button **55** is waterproof and the button's top outer surface is molded silicon rubber or similar soft pliable material. A retention detent **53** and tension detent **54** are molded along the edges of the top surface of the housing **50** to respectively engage the retention catch **26** and the tension clip **27** molded into non-conductive receptacle **25**. Other shapes, features, and conformities of the sealed housing **50** are possible.

The electrode patch **15** is intended to be disposable. The monitor recorder **14**, however, is reusable and can be transferred to successive electrode patches **15** to ensure continuity of monitoring. The placement of the wearable monitor **12** in a location at the sternal midline **16** (or immediately to either side of the sternum **13**) benefits long-term extended wear by removing the requirement that ECG electrodes be continually placed in the same spots on the skin throughout the monitoring period. Instead, the patient is free to place an electrode patch **15** anywhere within the general region of the sternum **13**.

As a result, at any point during ECG monitoring, the patient's skin is able to recover from the wearing of an electrode patch **15**, which increases patient comfort and satisfaction, while the monitor recorder **14** ensures ECG monitoring continuity with minimal effort. A monitor recorder **14** is merely unsnapped from a worn out electrode patch **15**, the worn out electrode patch **15** is removed from the skin, a new electrode patch **15** is adhered to the skin, possibly in a new spot immediately adjacent to the earlier location, and the same monitor recorder **14** is snapped into the new electrode patch **15** to reinitiate and continue the ECG monitoring.

During use, the electrode patch **15** is first adhered to the skin in the sternal region. FIG. **6** is a perspective view showing the extended wear electrode patch **15** of FIG. **4** without a monitor recorder **14** inserted. A flexible circuit **32** is adhered to each end of the flexible backing **20**. A distal circuit trace **33** and a proximal circuit trace (not shown) electrically couple ECG electrodes (not shown) to a pair of electrical pads **34**. The electrical pads **34** are provided within a moisture-resistant seal **35** formed on the bottom surface of the non-conductive receptacle **25**. When the monitor recorder **14** is securely received into the non-conductive receptacle **25**, that is, snapped into place, the electrical pads **34** interface to electrical contacts (not shown) protruding from the bottom surface of the monitor recorder **14**, and the moisture-resistant seal **35** enables the monitor recorder **14** to be worn at all times, even during bathing or other activities that could expose the monitor recorder **14** to moisture.

In addition, a battery compartment **36** is formed on the bottom surface of the non-conductive receptacle **25**, and a pair of battery leads (not shown) electrically interface the battery to another pair of the electrical pads **34**. The battery contained within the battery compartment **35** can be replaceable, rechargeable or disposable.

The monitor recorder **14** draws power externally from the battery provided in the non-conductive receptacle **25**, thereby uniquely obviating the need for the monitor recorder **14** to carry a dedicated power source. FIG. **7** is a bottom plan view of the monitor recorder **14** of FIG. **4**. A cavity **58** is formed on the bottom surface of the sealed housing **50** to accommodate the upward projection of the battery compartment **36** from the bottom surface of the non-conductive receptacle **25**, when the monitor recorder **14** is secured in place on the non-conductive receptacle **25**. A set of electrical contacts **56** protrude from the bottom surface of the sealed housing **50** and are arranged in alignment with the electrical pads **34** provided on the bottom surface of the non-conductive receptacle **25** to establish electrical connections between the electrode patch **15** and the monitor recorder **14**. In addition, a seal coupling **57** circumferentially surrounds the set of electrical contacts **56** and securely mates with the moisture-resistant seal **35** formed on the bottom surface of the non-conductive receptacle **25**.

The placement of the flexible backing **20** on the sternal midline **16** (or immediately to either side of the sternum **13**) also helps to minimize the side-to-side movement of the wearable monitor **12** in the left- and right-handed directions during wear. To counter the dislodgment of the flexible backing **20** due to compressional and torsional forces, a

layer of non-irritating adhesive, such as hydrocolloid, is provided at least partially on the underside, or contact, surface of the flexible backing **20**, but only on the distal end **30** and the proximal end **31**. As a result, the underside, or contact surface of the longitudinal midsection **23** does not have an adhesive layer and remains free to move relative to the skin. Thus, the longitudinal midsection **23** forms a crimp relief that respectively facilitates compression and twisting of the flexible backing **20** in response to compressional and torsional forces. Other forms of flexible backing crimp reliefs are possible.

Unlike the flexible backing **20**, the flexible circuit **32** is only able to bend and cannot stretch in a planar direction. The flexible circuit **32** can be provided either above or below the flexible backing **20**. FIG. **8** is a top view showing the flexible circuit **32** of the extended wear electrode patch **15** of FIG. **4** when mounted above the flexible backing **20**. A distal ECG electrode **38** and proximal ECG electrode **39** are respectively coupled to the distal and proximal ends of the flexible circuit **32**. A strain relief **40** is defined in the flexible circuit **32** at a location that is partially underneath the battery compartment **36** when the flexible circuit **32** is affixed to the flexible backing **20**. The strain relief **40** is laterally extendable to counter dislodgment of the ECG electrodes **38**, **39** due to tensile and torsional forces. A pair of strain relief cutouts **41** partially extend transversely from each opposite side of the flexible circuit **32** and continue longitudinally towards each other to define in 'S'-shaped pattern, when viewed from above. The strain relief respectively facilitates longitudinal extension and twisting of the flexible circuit **32** in response to tensile and torsional forces. Other forms of circuit board strain relief are possible.

ECG monitoring and other functions performed by the monitor recorder **14** are provided through a micro controlled architecture. FIG. **9** is a functional block diagram showing the component architecture of the circuitry **60** of the monitor recorder **14** of FIG. **4**. The circuitry **60** is externally powered through a battery provided in the non-conductive receptacle **25** (shown in FIG. **6**). Both power and raw ECG signals, which originate in the pair of ECG electrodes **38**, **39** (shown in FIG. **8**) on the distal and proximal ends of the electrode patch **15**, are received through an external connector **65** that mates with a corresponding physical connector on the electrode patch **15**. The external connector **65** includes the set of electrical contacts **56** that protrude from the bottom surface of the sealed housing **50** and which physically and electrically interface with the set of pads **34** provided on the bottom surface of the non-conductive receptacle **25**. The external connector includes electrical contacts **56** for data download, microcontroller communications, power, analog inputs, and a peripheral expansion port. The arrangement of the pins on the electrical connector **65** of the monitor recorder **14** and the device into which the monitor recorder **14** is attached, whether an electrode patch **15** or download station (not shown), follow the same electrical pin assignment convention to facilitate interoperability. The external connector **65** also serves as a physical interface to a download station that permits the retrieval of stored ECG monitoring data, communication with the monitor recorder **14**, and performance of other functions.

Operation of the circuitry **60** of the monitor recorder **14** is managed by a microcontroller **61**. The micro-controller **61** includes a program memory unit containing internal flash memory that is readable and writeable. The internal flash memory can also be programmed externally. The microcontroller **61** draws power externally from the battery provided on the electrode patch **15** via a pair of the electrical contacts **56**. The microcontroller **61** connects to the ECG front end circuit **63** that measures raw cutaneous electrical signals and generates an analog ECG signal representative of the electrical activity of the patient's heart over time.

The circuitry **60** of the monitor recorder **14** also includes a flash memory **62**, which the micro-controller **61** uses for storing ECG monitoring data and other physiology and information. The flash memory **62** also draws power externally from the battery provided on the electrode patch **15** via a pair of the electrical contacts **56**. Data is stored in a serial flash memory circuit, which supports read, erase and program operations over a communications bus. The flash memory **62** enables the microcontroller **61** to store digitized ECG data. The communications bus further enables the flash memory **62** to be directly accessed externally over the external connector **65** when the monitor recorder **14** is interfaced to a download station.

The circuitry **60** of the monitor recorder **14** further includes an actigraphy sensor **64** implemented as a 3-axis accelerometer. The accelerometer may be configured to generate interrupt signals to the microcontroller **61** by independent initial wake up and free fall events, as well as by device position. In addition, the actigraphy provided by the accelerometer can be used during post-monitoring analysis to correct the orientation of the monitor recorder **14** if, for instance, the monitor recorder **14** has been inadvertently installed upside down, that is, with the monitor recorder **14** oriented on the electrode patch **15** towards the patient's feet, as well as for other event occurrence analyses, such as described in commonly-assigned U.S. Pat. No. 9,737,224, issued Aug. 22, 2017, the disclosure of which is incorporated by reference.

The circuitry **60** of the monitor recorder **14** includes a wireless transceiver **69** that can provides wireless interfacing capabilities. The wireless transceiver **69** also draws power externally from the battery provided on the electrode patch **15** via a pair of the electrical contacts **56**. The wireless transceiver **69** can be implemented using one or more forms of wireless communications, including the IEEE 802.11 computer communications standard, that is Wi-Fi; the 4G mobile phone mobile communications standard; the Bluetooth data exchange standard; or other wireless communications or data exchange standards and protocols. The type of wireless interfacing capability could limit the range of interoperability of the monitor recorder **14**; for instance, Bluetooth-based implementations are designed for low power consumption with a short communications range.

The microcontroller **61** includes an expansion port that also utilizes the communications bus. External devices, separately drawing power externally from the battery provided on the electrode patch **15** or other source, can interface to the microcontroller **61** over the expansion port in half duplex mode. For instance, an external physiology sensor can be provided as part of the circuitry **60** of the monitor recorder **14**, or can be provided on the electrode patch **15** with communication with the micro-controller **61** provided over one of the electrical contacts **56**. The physiology sensor can include an SpO_2 sensor, blood pressure sensor, temperature sensor, respiratory rate sensor, glucose sensor, airflow sensor, volumetric pressure sensing, or other types of sensor or telemetric input sources. For instance, the integration of an airflow sensor is described in commonly-assigned U.S. Pat. No. 9,364,155, issued Jun. 14, 2016, the disclosure which is incorporated by reference.

Finally, the circuitry **60** of the monitor recorder **14** includes patient-interfaceable components, including a tactile feedback button **66**, which a patient can press to mark

events or to perform other functions, and a buzzer **67**, such as a speaker, magnetic resonator or piezoelectric buzzer. The buzzer **67** can be used by the microcontroller **61** to output feedback to a patient such as to confirm power up and initiation of ECG monitoring. Still other components as part of the circuitry **60** of the monitor recorder **14** are possible.

While the monitor recorder **14** operates under micro control, most of the electrical components of the electrode patch **15** operate passively. FIG. **10** is a functional block diagram showing the circuitry **70** of the extended wear electrode patch **15** of FIG. **4**. The circuitry **70** of the electrode patch **15** is electrically coupled with the circuitry **60** of the monitor recorder **14** through an external connector **74**. The external connector **74** is terminated through the set of pads **34** provided on the bottom of the non-conductive receptacle **25**, which electrically mate to corresponding electrical contacts **56** protruding from the bottom surface of the sealed housing **50** to electrically interface the monitor recorder **14** to the electrode patch **15**.

The circuitry **70** of the electrode patch **15** performs three primary functions. First, a battery **71** is provided in a battery compartment formed on the bottom surface of the non-conductive receptacle **25**. The battery **71** is electrically interfaced to the circuitry **60** of the monitor recorder **14** as a source of external power. The unique provisioning of the battery **71** on the electrode patch **15** provides several advantages. First, the locating of the battery **71** physically on the electrode patch **15** lowers the center of gravity of the overall wearable monitor **12** and thereby helps to minimize shear forces and the effects of movements of the patient and clothing. Moreover, the housing **50** of the monitor recorder **14** is sealed against moisture and providing power externally avoids having to either periodically open the housing **50** for the battery replacement, which also creates the potential for moisture intrusion and human error, or to recharge the battery, which can potentially take the monitor recorder **14** off line for hours at a time. In addition, the electrode patch **15** is intended to be disposable, while the monitor recorder **14** is a reusable component. Each time that the electrode patch **15** is replaced, a fresh battery is provided for the use of the monitor recorder **14**, which enhances ECG monitoring performance quality and duration of use. Finally, the architecture of the monitor recorder **14** is open, in that other physiology sensors or components can be added by virtue of the expansion port of the microcontroller **61**. Requiring those additional sensors or components to draw power from a source external to the monitor recorder **14** keeps power considerations independent of the monitor recorder **14**. Thus, a battery of higher capacity could be introduced when needed to support the additional sensors or components without effecting the monitor recorders circuitry **60**.

Second, the pair of ECG electrodes **38**, **39** respectively provided on the distal and proximal ends of the flexible circuit **32** are electrically coupled to the set of pads **34** provided on the bottom of the non-conductive receptacle **25** by way of their respective circuit traces **33**, **37**. The signal ECG electrode **39** includes a protection circuit **72**, which is an inline resistor that protects the patient from excessive leakage current.

Last, in a further embodiment, the circuitry **70** of the electrode patch **15** includes a cryptographic circuit **73** to authenticate an electrode patch **15** for use with a monitor recorder **14**. The cryptographic circuit **73** includes a device capable of secure authentication and validation. The cryptographic device **73** ensures that only genuine, non-expired, safe, and authenticated electrode patches **15** are permitted to provide monitoring data to a monitor recorder **14**, such as

described in commonly-assigned U.S. Pat. No. 9,655,538, issued May 23, 2017, the disclosure which is incorporated by reference.

In a further embodiment, the circuitry **70** of the electrode patch **15** includes a wireless transceiver **75**, in lieu the including of the wireless transceiver **69** in the circuitry **60** of the monitor recorder **14**, which interfaces with the microcontroller **61** over the microcontroller's expansion port via the external connector **74**.

The monitor recorder **14** continuously monitors the patient's heart rate and physiology. FIG. **11** is a flow diagram showing a monitor recorder-implemented method **100** for monitoring ECG data for use in the monitor recorder **14** of FIG. **4**. Initially, upon being connected to the set of pads **34** provided with the non-conductive receptacle **25** when the monitor recorder **14** is snapped into place, the microcontroller **61** executes a power up sequence (step **101**). During the power up sequence, the voltage of the battery **71** is checked, the state of the flash memory **62** is confirmed, both in terms of operability check and available capacity, and microcontroller operation is diagnostically confirmed. In a further embodiment, an authentication procedure between the microcontroller **61** and the electrode patch **15** are also performed.

Following satisfactory completion of the power up sequence, an iterative processing loop (steps **102-109**) is continually executed by the microcontroller **61**. During each iteration (step **102**) of the processing loop, the ECG frontend **63** (shown in FIG. **9**) continually senses the cutaneous ECG electrical signals (step **103**) via the ECG electrodes **38**, **29** and is optimized to maintain the integrity of the P-wave. A sample of the ECG signal is read (step **104**) by the microcontroller **61** by sampling the analog ECG signal output front end **63**. FIG. **12** is a graph showing, by way of example, a typical ECG waveform **110**. The x-axis represents time in approximate units of tenths of a second. The y-axis represents cutaneous electrical signal strength in approximate units of millivolts. The P-wave **111** has a smooth, normally upward, that is, positive, waveform that indicates atrial depolarization. The QRS complex usually begins with the downward deflection of a Q wave **112**, followed by a larger upward deflection of an R-wave **113**, and terminated with a downward waveform of the S wave **114**, collectively representative of ventricular depolarization. The T wave **115** is normally a modest upward waveform, representative of ventricular depolarization, while the U wave **116**, often not directly observable, indicates the recovery period of the Purkinje conduction fibers.

Sampling of the R-to-R interval enables heart rate information derivation. For instance, the R-to-R interval represents the ventricular rate and rhythm, while the P-to-P interval represents the atrial rate and rhythm. Importantly, the PR interval is indicative of atrioventricular (AV) conduction time and abnormalities in the PR interval can reveal underlying heart disorders, thus representing another reason why the P-wave quality achievable by the extended wear ambulatory electrocardiography and physiological sensor monitor described herein is medically unique and important. The long-term observation of these ECG indicia, as provided through extended wear of the wearable monitor **12**, provides valuable insights to the patient's cardiac function and overall well-being.

Each sampled ECG signal, in quantized and digitized form, is temporarily staged in buffer (step **105**), pending compression preparatory to storage in the flash memory **62** (step **106**). Following compression, the compressed ECG digitized sample is again buffered (step **107**), then written to

the flash memory **62** (step **108**) using the communications bus. Processing continues (step **109**), so long as the monitoring recorder **14** remains connected to the electrode patch **15** (and storage space remains available in the flash memory **62**), after which the processing loop is exited and execution terminates. Still other operations and steps are possible.

In a further embodiment, the monitor recorder **14** also continuously receives data from wearable physiology and activity sensors **131** and wearable or mobile communications devices **133** (shown in FIG. **3**). The data is received in a conceptually-separate execution thread as part of the iterative processing loop (steps **102**-**109**) continually executed by the microcontroller **61**. During each iteration (step **102**) of the processing loop, if wireless data is available (step **140**), a sample of the wireless is read (step **141**) by the microcontroller **61** and, if necessary, converted into a digital signal by the onboard ADC of the microcontroller **61**. Each wireless data sample, in quantized and digitized form, is temporarily staged in buffer (step **142**), pending compression preparatory to storage in the flash memory **62** (step **143**). Following compression, the compressed wireless data sample is again buffered (step **144**), then written to the flash memory **62** (step **145**) using the communications bus. Processing continues (step **109**), so long as the monitoring recorder **14** remains connected to the electrode patch **15** (and storage space remains available in the flash memory **62**), after which the processing loop is exited and execution terminates. Still other operations and steps are possible.

The monitor recorder **14** stores ECG data and other information in the flash memory **62** (shown in FIG. **9**) using a proprietary format that includes data compression. As a result, data retrieved from a monitor recorder **14** must first be converted into a format suitable for use by third party post-monitoring analysis software. FIG. **13** is a flow diagram showing a method **150** for offloading and converting ECG and other physiological data from an extended wear electrocardiography and physiological sensor monitor **12** in accordance with one embodiment. The method **150** can be implemented in software and execution of the software can be performed on a download station **125**, which could be a programmer or other device, or a computer system, including a server **122** or personal computer **129**, such as further described supra with reference to FIG. **3**, as a series of process or method modules or steps. For convenience, the method **150** will be described in the context of being performed by a personal computer **136** or other connectable computing device (shown in FIG. **3**) as middleware that converts ECG data and other information into a format suitable for use by a third-party post-monitoring analysis program. Execution of the method **150** by a computer system would be analogous mutatis mutandis.

Initially, the download station **125** is connected to the monitor recorder **14** (step **151**), such as by physically interfacing to a set of terminals **128** on a paired receptacle **127** or by wireless connection, if available. The data stored on the monitor recorder **14**, including ECG and physiological monitoring data, other recorded data, and other information are retrieved (step **152**) over a hard link **135** using a control program **137** ("Ctl") or analogous application executing on a personal computer **136** or other connectable computing device.

The data retrieved from the monitor recorder **14** is in a proprietary storage format and each datum of recorded ECG monitoring data, as well as any other physiological data or other information, must be converted, so that the data can be used by a third-party post-monitoring analysis program. Each datum of ECG monitoring data is converted by the middleware (steps **153**-**159**) in an iterative processing loop. During each iteration (step **153**), the ECG datum is read (step **154**) and, if necessary, the gain of the ECG signal is adjusted (step **155**) to compensate, for instance, for relocation or replacement of the electrode patch **15** during the monitoring period.

In addition, depending upon the configuration of the wearable monitor **12**, other physiological data (or other information), including patient events, such as a fall, peak activity level, sleep detection, Detection of patient activity levels and states, and so on, may be recorded along with the ECG monitoring data. For instance, actigraphy data may have been sampled by the actigraphy sensor **64** based on a sensed event occurrence, such as a sudden change in orientation due to the patient taking a fall. In response, the monitor recorder **14** will embed the actigraphy data samples into the stream of data, including ECG monitoring data, that is recorded to the flash memory **62** by the micro-controller **61**. Post-monitoring, the actigraphy data is temporally matched to the ECG data to provide the proper physiological context to the sensed event occurrence. As a result, the three-axis actigraphy signal is turned into an actionable event occurrence that is provided, through conversion by the middleware, to third party post-monitoring analysis programs, along with the ECG recordings contemporaneous to the event occurrence. Other types of processing of the other physiological data (or other information) are possible.

Thus, during execution of the middleware, any other physiological data (or other information) that has been embedded into the recorded ECG monitoring data is read (step **156**) and time-correlated to the time frame of the ECG signals that occurred at the time that the other physiological data (or other information) was noted (step **157**). Finally, the ECG datum, signal gain adjusted, if appropriate, and other physiological data, if applicable and as time-correlated, are stored in a format suitable to the backend software (step **158**) used in post-monitoring analysis.

In a further embodiment, the other physiological data, if apropos, is embedded within an unused ECG track. For example, the SCP-ENG standard allows multiple ECG channels to be recorded into a single ECG record. The monitor recorder **14**, though, only senses one ECG channel. The other physiological data can be stored into an additional ECG channel, which would otherwise be zero-padded or altogether omitted. The backend software would then be able to read the other physiological data in context with the single channel of ECG monitoring data recorded by the monitor recorder **14**, provided the backend software implemented changes necessary to interpret the other physiological data. Still other forms of embedding of the other physiological data with formatted ECG monitoring data, or of providing the other physiological data in a separate manner, are possible.

Processing continues (step **159**) for each remaining ECG datum, after which the processing loop is exited and execution terminates. Still other operations and steps are possible.

While the invention has been particularly shown and described as referenced to the embodiments thereof, those skilled in the art will understand that the foregoing and other changes in form and detail may be made therein without departing from the spirit and scope.

What is claimed is:

1. A wearable electrocardiography monitoring device, comprising:

a flexible backing including a strip comprising:

a first face and a second face, wherein a portion of the first face is covered in adhesive to adhere the strip to skin of a patient,

a first end section,

a second end section opposite the first end section, and

a mid-section between the first end section and the second end section;

a flexible circuit mounted to the second face of the strip, the flexible circuit comprising a first circuit trace and a second circuit trace;

a first electrocardiographic electrode and a second electrocardiographic electrode, wherein the first electrocardiographic electrode and the second electrocardiographic electrode are configured to sense electrocardiographic signals, wherein the first electrocardiographic electrode and the second electrocardiographic electrode are coupled to the flexible circuit, wherein the first electrocardiographic electrode is conductively exposed at the first face along the first end section of the strip, wherein the second electrocardiographic electrode is conductively exposed at the first face along the second end section of the strip, wherein the first circuit trace is electrically coupled to the first electrocardiographic electrode, and wherein the second circuit trace is electrically coupled to the second electrocardiographic electrode;

a battery;

a wireless transceiver;

a button configured to be pressed to mark an event;

a sealed housing having rounded edges on a top surface, wherein the sealed housing is coupled to the flexible backing, and wherein the sealed housing includes a processor, wherein the processor is electrically coupled to the first electrocardiographic electrode, the second electrocardiographic electrode, and the battery, wherein the processor is configured to process the electrocardiographic signals sensed via the first electrocardiographic electrode and the second electrocardiographic electrode.

2. The wearable electrocardiography monitoring device of claim **1**, wherein the mid-section comprises a first edge parallel to a second edge.

3. The wearable electrocardiography monitoring device of claim **1**, wherein the wireless transceiver is configured to communicate with an external device via Wi-Fi, mobile phone communication standards, or Bluetooth.

4. The wearable electrocardiography monitoring device of claim **1**, wherein the electrocardiographic signals are converted to a different format.

5. The wearable electrocardiography monitoring device of claim **4**, wherein the electrocardiographic signals are retrieved by one of a server, a client computer, and a mobile device via the wireless transceiver after the electrocardiographic signals are converted to the different format.

6. The wearable electrocardiography monitoring device of claim **1**, wherein the adhesive covering the portion of the first face of the strip is provided on the first end section and the second end section only.

7. The wearable electrocardiography monitoring device of claim **1**, wherein the battery is vertically aligned with the wireless transceiver.

8. A wearable electrocardiography monitoring device, comprising:

a flexible backing including a strip comprising:

a first face and a second face, wherein a portion of the first face is covered in adhesive to adhere the strip to skin of a patient,

a first end section,

a second end section opposite the first end section, and

a mid-section between the first end section and the second end section, wherein the mid-section is narrower than the first end section and the second end section;

a flexible circuit mounted to the second face of the strip, the flexible circuit comprising a first circuit trace and a second circuit trace;

a first electrocardiographic electrode and a second electrocardiographic electrode, wherein the first electrocardiographic electrode and the second electrocardiographic electrode are configured to sense electrocardiographic signals, wherein the first electrocardiographic electrode and the second electrocardiographic electrode are coupled to the flexible circuit, wherein the first electrocardiographic electrode is conductively exposed at the first face along the first end section of the strip, wherein the second electrocardiographic electrode is conductively exposed at the first face along the second end section of the strip, wherein the first circuit trace is electrically coupled to the first electrocardiographic electrode, wherein the second circuit trace is electrically coupled to the second electrocardiographic electrode, and wherein the first electrocardiographic electrode includes an inline resistor;

a battery;

a wireless transceiver;

a button configured to be pressed to mark an event;

a sealed housing having rounded edges on a top surface, wherein the sealed housing is coupled to the flexible backing, and wherein the sealed housing includes a processor, wherein the processor is electrically coupled to the first electrocardiographic electrode, the second electrocardiographic electrode, and the battery, wherein the processor is configured to process the electrocardiographic signals sensed via the first electrocardiographic electrode and the second electrocardiographic electrode.

9. The wearable electrocardiography monitoring device of claim **8**, wherein the battery is vertically aligned with the sealed housing.

10. The wearable electrocardiography monitoring device of claim **8**, wherein the wireless transceiver is configured to communicate with an external device via Wi-Fi, mobile phone communication standards, or Bluetooth.

11. The wearable electrocardiography monitoring device of claim **8**, wherein the electrocardiographic signals are converted to a different format.

12. The wearable electrocardiography monitoring device of claim **11**, wherein the electrocardiographic signals are retrieved by one of a server, a client computer, and a mobile device via the wireless transceiver after the electrocardiographic signals are converted to the different format.

13. The wearable electrocardiography monitoring device of claim **8**, wherein the adhesive covering the portion of the first face of the strip is provided on the first end section and the second end section only.

14. The wearable electrocardiography monitoring device of claim **8**, wherein the battery is vertically aligned with the wireless transceiver.

15. A wearable electrocardiography monitoring device, comprising:

a flexible backing comprising:

a first face and a second face, wherein the first face includes an adhesive to adhere the flexible backing to skin of a patient;

a first end section opposite a second end section, wherein a mid-section is disposed between the first end section and the second end section, wherein the mid-section is narrower than the first end section and the second end section, and wherein the mid-section includes a first edge parallel to a second edge; and

a flexible circuit, wherein the flexible circuit comprises a first circuit trace and a second circuit trace on the second face of the flexible backing;

a first electrocardiographic electrode configured to sense electrocardiographic signals, wherein the first electrocardiographic electrode is conductively exposed at the first face along the second end section of the flexible backing, and wherein the first electrocardiographic electrode is electrically coupled to the first circuit trace;

a second electrocardiographic electrode configured to sense electrocardiographic signals, wherein the second electrocardiographic electrode is conductively exposed at the first face along the first end section of the flexible backing, and wherein the second electrocardiographic electrode is electrically coupled to the second circuit trace;

a sealed housing having rounded edges on a top surface, wherein the sealed housing is coupled to the flexible backing, wherein the sealed housing includes a processor, wherein the processor is electrically coupled to the first electrocardiographic electrode and the second electrocardiographic electrode, wherein the processor is configured to process the electrocardiographic signals sensed via the first electrocardiographic electrode and the second electrocardiographic electrode;

a button disposed on the top surface of the sealed housing, wherein the button is configured to be pressed to mark an event;

a battery disposed between the processor and the skin of the patient, the battery configured to provide power to the processor of the sealed housing; and

a wireless transceiver configured to communicate at least a portion of the electrocardiographic signals.

16. The wearable electrocardiography monitoring device of claim **15**, wherein the wireless transceiver is configured to communicate with an external device via Wi-Fi, mobile phone communication standards, or Bluetooth.

17. The wearable electrocardiography monitoring device of claim **15**, wherein the electrocardiographic signals are converted to a different format.

18. The wearable electrocardiography monitoring device of claim **17**, wherein the electrocardiographic signals are retrieved by one of a server, a client computer, and a mobile device via the wireless transceiver after the electrocardiographic signals are converted to the different format.

19. The wearable electrocardiography monitoring device of claim **15**, wherein the adhesive covering the portion of the first face is provided on the first end section and the second end section only.

20. The wearable electrocardiography monitoring device of claim **15**, wherein the battery is vertically aligned with the wireless transceiver.

21. The wearable electrocardiography monitoring device of claim **15**,

wherein the wireless transceiver is configured to communicate with an external device via Wi-Fi, mobile phone communication standards, or Bluetooth,

wherein the electrocardiographic signals are converted to a different format,

wherein the electrocardiographic signals are retrieved by one of a server, a client computer, and a mobile device

via the wireless transceiver after the electrocardiographic signals are converted to the different format,

wherein the adhesive covering the portion of the first face is provided on the first end section and the second end section only, and

wherein the battery is vertically aligned with the wireless transceiver.

22. The wearable electrocardiography monitoring device of claim **15**,

wherein the wireless transceiver is configured to communicate with an external device via Wi-Fi, mobile phone communication standards, or Bluetooth,

wherein the electrocardiographic signals are retrieved by one of a server, a client computer, and a mobile device via the wireless transceiver after the electrocardiographic signals are converted to a different format,

wherein the adhesive covering the portion of the first face is provided on the first end section and the second end section only, and

wherein the battery is vertically aligned with the wireless transceiver.

23. The wearable electrocardiography monitoring device of claim **15**,

wherein the wireless transceiver is configured to communicate with an external device via Wi-Fi, mobile phone communication standards, or Bluetooth,

wherein the electrocardiographic signals are converted to a different format,

wherein the adhesive covering the portion of the first face is provided on the first end section and the second end section only, and

wherein the battery is vertically aligned with the wireless transceiver.

24. The wearable electrocardiography monitoring device of claim **15**,

wherein the wireless transceiver is configured to communicate with an external device via Wi-Fi, mobile phone communication standards, or Bluetooth,

wherein the electrocardiographic signals are converted to a different format,

wherein the electrocardiographic signals are retrieved by one of a server, a client computer, and a mobile device via the wireless transceiver after the electrocardiographic signals are converted to the different format, and

wherein the battery is vertically aligned with the wireless transceiver.

25. The wearable electrocardiography monitoring device of claim **15**,

wherein the wireless transceiver is configured to communicate with an external device via Wi-Fi, mobile phone communication standards, or Bluetooth,

wherein the electrocardiographic signals are converted to a different format,

wherein the electrocardiographic signals are retrieved by one of a server, a client computer, and a mobile device via the wireless transceiver after the electrocardiographic signals are converted to the different format, and

wherein the adhesive covering the portion of the first face is provided on the first end section and the second end section only.

26. The wearable electrocardiography monitoring device of claim **15**,

wherein the wireless transceiver is configured to communicate with an external device via Wi-Fi, mobile phone communication standards, or Bluetooth,

wherein the electrocardiographic signals are converted to a different format, and

wherein the electrocardiographic signals are retrieved by one of a server, a client computer, and a mobile device via the wireless transceiver after the electrocardiographic signals are converted to the different format.

27. The wearable electrocardiography monitoring device of claim **15**,

wherein the wireless transceiver is configured to communicate with an external device via Wi-Fi, mobile phone communication standards, or Bluetooth,

wherein the electrocardiographic signals are converted to a different format, and

wherein the adhesive covering the portion of the first face is provided on the first end section and the second end section only.

28. The wearable electrocardiography monitoring device of claim **15**,

wherein the wireless transceiver is configured to communicate with an external device via Wi-Fi, mobile phone communication standards, or Bluetooth,

wherein the electrocardiographic signals are converted to a different format, and

wherein the battery is vertically aligned with the wireless transceiver.

29. The wearable electrocardiography monitoring device of claim **15**,

wherein the wireless transceiver is configured to communicate with an external device via Wi-Fi, mobile phone communication standards, or Bluetooth,

wherein the electrocardiographic signals are retrieved by one of a server, a client computer, and a mobile device via the wireless transceiver after the electrocardiographic signals are converted to a different format, and

wherein the adhesive covering the portion of the first face is provided on the first end section and the second end section only.

30. The wearable electrocardiography monitoring device of claim **15**,

wherein the wireless transceiver is configured to communicate with an external device via Wi-Fi, mobile phone communication standards, or Bluetooth,

wherein the electrocardiographic signals are retrieved by one of a server, a client computer, and a mobile device via the wireless transceiver after the electrocardiographic signals are converted to a different format, and

wherein the battery is vertically aligned with the wireless transceiver.

* * * * *

Exhibit 3

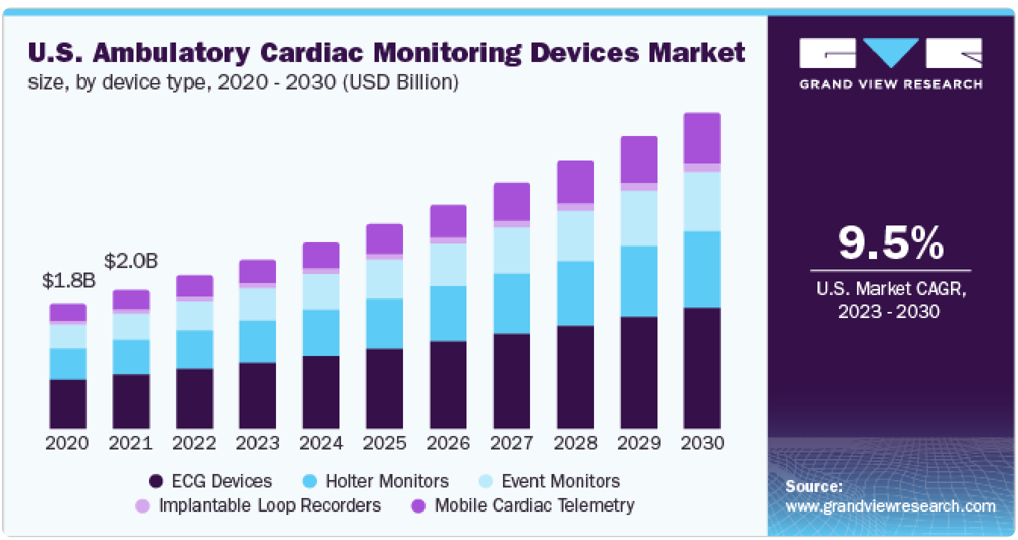
PDF
Market Analysis Report

Ambulatory Cardiac Monitoring Devices Market Size, Share & Trends Analysis Report By Device Type (ECG Devices, Holter Monitors, Event Monitors), By End-use, By Region, And Segment Forecasts, 2023 - 2030

Report ID: GVR-4-68040-033-2 | Number of Pages: 90 | Format: Electronic (PDF)
Historical Range: 2017 - 2020 | Industry: Healthcare (/industry/healthcare)

Report Overview

The global ambulatory cardiac monitoring devices market size was valued at USD 5.77 billion in 2022 and is expected to expand at a compound annual growth rate (CAGR) of 10.4% over the forecast period from 2023 to 2030. This is attributed to the increasing geriatric population and rising investments in R&D by key market players. Moreover, rising incidences of cardiac disorders such as arrhythmia, coupled with the presence of robust reimbursement and regulatory policies in developed and emerging nations, are expected to contribute towards the growth of the market over the forecast period. The COVID-19 pandemic had a detrimental effect on the ambulatory cardiac monitoring devices market due to the lockdowns imposed by governments, limits on elective cardiac procedures, and the general strain on hospitals.



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In the post-pandemic scenario, the rising awareness regarding the benefits associated with the adoption of ambulatory cardiac monitoring devices for continuous remote patient monitoring is driving market growth. For instance, according to a study published on NCBI in March 2022, the frequency of in-office consulting was lower during the pandemic period. Around two-thirds of the participants in the survey adopted remote cardiac monitoring solutions.

The increasing adoption of a sedentary lifestyle is contributing to the rising incidences of heart disease, which in turn is driving the market growth. For instance, according to the CDC, around 25% of adults are not active at all and around 60% do not engage in the recommended 150 minutes of activities every week. A sedentary lifestyle is one of the major reasons that cause heart disease.

Device Insights

Based on devices, the market is segmented into Holter monitors, ECG devices, event monitors, mobile cardiac telemetry, and implantable loop recorders. The ECG devices segment accounted for the largest market share of 38.9% in 2022. The demand for ECG devices is expected to grow due to the increasing incidences of cardiovascular disease & hypertension worldwide, coupled with the ease of access, continuous monitoring, and high accuracy capabilities of the device. According to a study conducted by the WHO, 17.9 million people die every year due to cardiovascular diseases, which accounts for 32% of the total deaths globally.

The mobile cardiac telemetry (MCT) segment is expected to show the fastest CAGR of 13.2% over the forecast period. The demand for MCT monitors is expected to grow due to a rising preference for on-the-go monitoring devices. Ambulatory monitoring is beneficial in the case of Atrial Fibrillation (AF) monitoring, which may further lead to a heart attack. According to a study conducted by NCBI in 2022, AF is expected to affect 19.6% of patients over 65 years of age by 2030, and this estimation is expected to double by 2050.

Report Coverage & Deliverables

End-use Insights

Based on end-use, the market is segmented into ambulatory care centers, hospitals & clinics, and others. The hospitals & clinics segment dominated the market with a share of 50.5% in 2022. This is attributed to the rising incidence of cardiovascular disorders and the growing need for continuous supervision in critical cardiac situations. According to the CDC, in 2020, around 697,000 people died due to heart disease, of which around 382,820 people died due to Coronary Artery Disease (CAD). In addition, in the same year, around 20 million adults aged 20 and above were diagnosed with CAD.

Global ambulatory cardiac monitoring devices market share, by end-use, 2022 (%)

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The ambulatory care centers segment is expected to expand at a CAGR of 10.3% during the forecast period. The increasing geriatric population is propelling the market demand for the segment, as people above 65 years of age are more vulnerable to heart-related conditions. According to a study conducted by WHO, the geriatric population is expected to increase from 1.4 billion in 2020 to 2.1 billion by 2050. Ambulatory care centers cater to the interests of geriatric people as they provide a more efficient, convenient, and cost-effective alternative to hospital-based outpatient procedures

Regional Insights

North America dominated the global ambulatory cardiac monitoring devices market with a share of 42.8% in 2022. This is attributed to the key market players engaging in collaborations and partnerships to strengthen their market position in the region, coupled with the presence of a well-structured regulatory framework and reimbursement scenario in the region. For instance, in October 2022, GE Healthcare announced a collaboration with AMC Health for the integration of AMC Health's RPM platform into GE's existing product portfolio.

Ambulatory Cardiac Monitoring Devices Market Trends by Region

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Asia Pacific is expected to witness the fastest CAGR of 11.3% over the forecast period. The key players are engaging in partnerships, collaborations, product launches, and acquisitions to strengthen their position in the market. Moreover, manufacturers are also investing in safeguarding personal patient data by making ambulatory cardiac monitoring platforms threat-proof from cyber-attacks.

Key Companies & Market Share Insights

Major market players are engaging in partnerships, acquisitions, and collaborations, to increase their market share. For instance, in February 2021, Koninklijke Philips N.V. announced the acquisition of BioTelemetry, Inc., a cardiac monitoring and diagnostics provider in the U.S. This acquisition is expected to strengthen Philips' cardiac care product portfolio by adding BioTelemetry's Holter monitoring for short-term & long-term administration, Mobile Cardiac Outpatient Telemetry, and Event Recorder solutions. Some of the prominent players in the global ambulatory cardiac monitoring devices market include:

- Koninklijke Philips N.V
- Hill-rom Services, Inc.
- Shenzhen Mindray Bio-Medical Electronics Co., Ltd.
- ZOLL Medical Corporation
- NIHON KOHDEN CORPORATION
- FUKUDA DENSHI

- iRhythm Technologies Inc,
- Biotronik SE & Co. KG
- General Electric Company
- Abbott

Ambulatory Cardiac Monitoring Devices Market Report Scope

Report Attribute	Details
Market size value in 2023	USD 6.42 billion
Revenue forecast in 2030	USD 12.72 billion
Growth rate	CAGR of 10.4% from 2023 to 2030
Base year for estimation	2022
Historical data	2017 - 2021
Forecast period	2023 - 2030
Quantitative units	Revenue in USD million and CAGR from 2023 to 2030
Report coverage	Revenue forecast, company share, competitive landscape, growth factors & trends
Segments covered	Device, end-use, region
Regional scope	North America; Europe; Asia Pacific; Latin America; MEA
Country scope	U.S.; Canada; UK; Germany; France; Italy; Spain; Denmark; Sweden; Norway; China; Japan; India; Australia; South Korea; Thailand; Brazil; Mexico; Argentina; South Africa; Saudi Arabia; UAE; Kuwait
Key Companies Profiled	Koninklijke Philips N.V; Hill-rom Services, Inc.; Shenzhen Mindray Bio-Medical Electronics Co., Ltd.; ZOLL Medical Corporation; NIHON KOHDEN CORPORATION; FUKUDA DENSHI; iRhythm Technologies Inc,; Biotronik SE & Co. KG; General Electric Company; Abbott
Customization scope	Free report customization (equivalent up to 8 analysts working days) with purchase. Addition or alteration to country, regional, and segment scope.
Pricing and purchase options	Avail customized purchase options to meet your exact research needs. Explore purchase options (https://www.grandviewresearch.com/checkout/select-license/ambulatory-cardiac-monitoring-devices-market-report)

Global Ambulatory Cardiac Monitoring Devices Market Segmentation

This report forecasts revenue growth at the global, regional, and country levels and provides an analysis of the latest industry trends in each of the sub-segments from 2017 to 2030. For this study, Grand View Research has segmented the global ambulatory cardiac monitoring devices market report based on device type, end-use, and region:

Global Ambulatory Cardiac Monitoring Devices Market Segmentation

To learn more about this report, request a free sample copy (/industry-analysis/ambulatory-cardiac-monitoring-devices-market-report/request/rs5)

- **Device Type Outlook (Revenue, USD Million, 2017 - 2030)**
  - ECG Devices
  - Holter Monitors
  - Event Monitors
  - Implantable Loop recorders
  - Mobile Cardiac Telemetry
- **End-use Outlook (Revenue, USD Million, 2017 - 2030)**
  - Ambulatory Care Centers
  - Hospitals & Clinics
  - Others
- **Regional Outlook (Revenue, USD Million, 2017 - 2030)**
  - North America
    - U.S.
    - Canada
  - Europe
    - U.K.
    - Germany
    - France
    - Italy
    - Spain
    - Denmark

- Sweden
- Norway
- Asia Pacific
  - China
  - Japan
  - India
  - Australia
  - South Korea
  - Thailand
- Latin America
  - Brazil
  - Mexico
  - Argentina
- Middle East & Africa
  - South Africa
  - Saudi Arabia
  - UAE
  - Kuwait

Frequently Asked Questions About This Report

Who are the key players in the ambulatory cardiac monitoring devices market?

What are the factors driving the ambulatory cardiac monitoring devices market?

How big is the ambulatory cardiac monitoring devices market?

What is the ambulatory cardiac monitoring devices market growth?

Which region accounted for the largest ambulatory cardiac monitoring devices market share?

Key questions answered by the report

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Office Address

Grand View Research is registered in the State of California at Grand View Research, Inc. 201 Spear Street 1100, San Francisco, CA 94105, United States

+1-415-349-0058 (tel:1-415-349-0058) or 1-888-202-9519 (tel:1-888-202-9519)

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Exhibit 4

The Zio® service monitoring solutions. One mission: **precision**.

Comfort. Ease. Accuracy. Zio ECG monitors are designed to provide high-quality, accurate data with astounding patient compliance. [1-4]

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Next-generation Zio® monitor

Long-Term Continuous Monitoring Service

Introducing the Zio monitor—designed to be lighter, smaller, and thinner, while building on the high performance of Zio XT.[5-8]

Zio® XT

Long-Term Continuous Monitoring Service

The monitor that changed the game. Zio XT monitoring service provides continuous, uninterrupted recording and a comprehensive end-of-wear report.[9]

Zio AT®

Mobile Cardiac Telemetry (MCT) Monitoring Service

The Zio AT MCT monitoring service provides continuous, uninterrupted recording, actionable wear-time reports, and a comprehensive end-of-wear report.[10-13]

In a large real-world evidence study, Zio long-term continuous monitoring (LTCM) service is associated with[6-8,14]

lowest likelihood of retesting

fastest time to clinical diagnosis

lowest acute healthcare resource utilization

Zio LTCM service is more likely to detect specified arrhythmias.[6-8,14]

96%

more likely vs Holter monitoring services

72%
more likely vs event monitoring services

25%
more likely v
other LTCM
services

Zio Monitor | Zio XT | Zio AT

Long-term continuous monitoring service

The new Zio monitor is designed with patients in mind by providing a more breathable, inconspicuous, and comfortable wear experience so patients can go about their daily activities.[5,15,16]

72%
Smaller[5,17]

62%
Lighter[5]

23%
Thinner[5]

Compared to Zio XT Device

Perfecting the experience is at the heart of the Zio service.

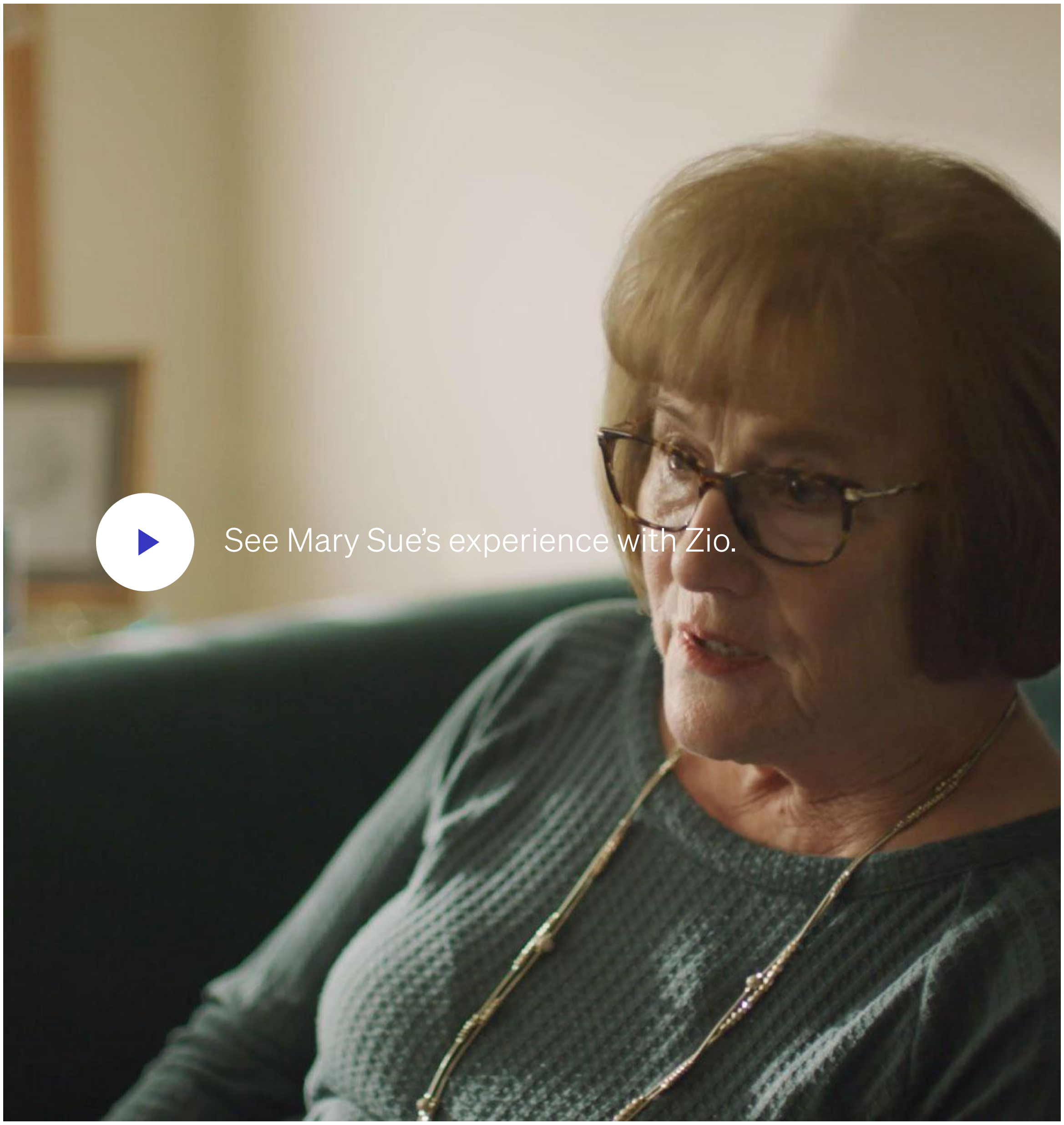
Comfortable and easy-to-use with no charging or electrode manipulations needed.[9,10,16,18,19]

Patients can:

Exercise[20]

Shower[20]

Sleep



The Zio Service | Zio ECG Monitors | Reporting

Patient Management | Case Studies

Let's talk.

We'd love to know how we can help you and your patients.

What best describes your role?*

What can we help you with?*

Provide additional information

Email*

Company name*

First name*

Last name*

Postal code*

Phone number

I acknowledge and agree that iRhythm Technologies, Inc., iRhythm Technologies, Ltd. or an authorized representative (collectively, "iRhythm") may store and process my personal information in accordance with the terms of iRhythm's Privacy Policy. By submitting this form, you consent to iRhythm contacting you for purposes of marketing its products, services, and events. You may unsubscribe at any time. For more information about iRhythm's processing of your personal information, you may review our Privacy Policy.*

Let's talk

1 99% of physicians agree with the comprehensive final patient report. Based on a review of all online Zio XT and AT final patient reports.

2 Data on file. iRhythm Technologies; 2021.

3 Data on file. iRhythm Technologies; 2022.

4 Data on file. iRhythm Technologies; 2021-2022.

5 Data on file. iRhythm Technologies; 2023.

6 Reynolds MR, Passman RS, Swindle JP, et al. Comparative effectiveness of ambulatory monitors for arrhythmia diagnosis: a retrospective analysis of Medicare beneficiaries. Presented at: ACC 2023; March 3-4, 2023; New Orleans, LA.

7 In testing for specified arrhythmias defined by Hierarchical Condition Categories (HCC) 96.

8 Based on previous generation Zio XT device data. Zio monitor utilizes the same

14 Zio LTCM service refers to Zio XT and Zio monitor service.

15 Data on file. iRhythm Technologies; 2017, 2023.

16 Data on file. iRhythm Technologies; 2021, 2022.

17 Volume reflected in the device housing.

18 Zio monitor Clinical Reference Manual. iRhythm Technologies; 2021.

19 Zio AT does not require battery changes or charging. Zio AT has wear time transmission limits and is contraindicated for critical care patients. Refer to the Zio AT Clinical Reference Manual for additional information.

20 The Zio monitor patch should not be submerged in water. During a bath, keep the device above water. Please refer to the Zio monitor labeling instructions or Patient Guide for the full set of details.

operating principles and ECG algorithm. Additional data on file.

9 Zio XT Clinical Reference Manual. iRhythm Technologies; 2019.

10 Zio AT Clinical Reference Manual. iRhythm Technologies; 2020.

11 Continuous, uninterrupted refers to the recording of ECG data. Zio AT Gateway transmissions may be impacted by a variety of factors. See product labeling for more information.

12 Zio AT is contraindicated for critical care patients.

13 Do not use Zio AT for patients with symptomatic episodes where variations in cardiac performance could result in immediate danger to the patient or when real-time or in-patient monitoring should be prescribed. Refer to the Zio AT labeling and Clinical Reference Manual for full contraindications.

21 Tsang JP, Mohan S. Benefits of monitoring patients with mobile cardiac telemetry (MCT) compared with the Event or Holter monitors. Med Devices (Auckl). 2014;7-5

22 Data on file. iRhythm Technologies; 2022-2023.

23 Diagnostic yield refers to data collected from monitoring devices with arrhythmias (rule-in).

24 Eysenck W, Freemantle N, Sulke N. A randomized trial evaluating the accuracy of AF detection by four external ambulatory ECG monitors compared to permanent pacemaker AF detection. J Interv Card Electrophysiol. 2020;57(3):361-369.

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Exhibit 5

DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

iRhythm Technologies, Inc.
c/o Mr. Michael S. Righter
Manager of Quality Assurance and Regulatory Affairs
650 Townsend Street
Suite 380
San Francisco, CA 94103

JUL 18 2012

Re: K121319
Trade/Device Name: Zio® Patch
Regulation Number: 21 CFR 870.2800
Regulation Name: Medical Magnetic Tape Recorder
Regulatory Class: Class II (two)
Product Codes: DSH
Dated: May 1, 2012
Received: May 2, 2012

Dear Mr. Righter:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must

comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

iRhythm

INDICATIONS FOR USE STATEMENT

510(k) Number: K121319

Device Names: Zio® Patch

Indications for Use:

The Zio® Patch is a prescription-only, single-patient-use, continuously recording ECG monitor that can be worn up to 14 days. It is indicated for use on patients who may be asymptomatic or who may suffer from transient symptoms such as palpitations, shortness of breath, dizziness, light-headedness, pre-syncope, syncope, fatigue, or anxiety.

Prescription Use ____X____
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use ________
(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE—CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K121319

650 Townsend Street, Suite 380 | San Francisco, CA 94103 | (415) 632-5700 T | (415) 632-5701 F | www.irhythmtech.com

Exhibit 6

U.S. FOOD & DRUG ADMINISTRATION

August 29, 2018

iRhythm Technologies, Inc.
Rich Laguna
Director of Quality and Regulatory Affairs
650 Townsend Street, Suite 500
San Francisco, California 94103

Re: K181502
Trade/Device Name: Zio AT ECG Monitoring System
Regulation Number: 21 CFR 870.2800
Regulation Name: Medical Magnetic Tape Recorder
Regulatory Class: Class II
Product Code: DSH, DQK, DSI, DXH
Dated: June 5, 2018
Received: June 7, 2018

Dear Rich Laguna:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part

801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Arielle Drummond -S

for
Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K181502

Device Name
Zio AT ECG Monitoring System

Indications for Use *(Describe)*
The device is intended to capture, analyze and report symptomatic and asymptomatic cardiac events and continuous electrocardiogram information for long-term monitoring. While continuously recording patient ECG, both patient-triggered and automatically-detected arrhythmia events are transmitted to a monitoring center for reporting. After wear, a final report is generated based on the beat-to-beat information from the entire ECG recording. It is indicated for use on patients 18 years or older who may be asymptomatic or who may suffer from transient symptoms such as palpitations, shortness of breath, dizziness, light-headedness, pre-syncope, syncope, fatigue, or anxiety and patients who are asymptomatic. The reports are provided for review by the intended user to render a diagnosis based on clinical judgment and experience. It is not intended for use on critical care patients.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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SECTION 5. 510(k) Summary

1. GENERAL INFORMATION

510(k) Sponsor

iRhythm Technologies, Inc.

650 Townsend Street, Suite 500

San Francisco, CA. 94103

Correspondence Person

Rich Laguna

Director of Quality and Regulatory Affairs

Contact Information

Email: rlaguna@irhythmtech.com

Phone: (415) 632-5749

Date Prepared

08/29/2018

2. PROPOSED DEVICE

Proprietary Name

Zio® AT ECG Monitoring System

Common Name

Zio® AT ECG Monitoring System

Classification Name

Medical magnetic tape recorder [21 CFR§870.2800]

Programmable diagnostic computer [21CFR§870.1425]

Telephone electrocardiograph transmitter and receiver [21CFR§870.2920]

Arrhythmia detector and alarm (including ST-segment measurement and alarm) [21 CFR§870.1025]

Regulatory Class

Class II

Product Codes

DSH, Recorder, Magnetic Tape, Medical

DQK, Computer, Diagnostic, Programmable

DXH, Transmitters And Receivers, Electrocardiograph, Telephone

DSI, Detector And Alarm, Arrhythmia

3. PREDICATE DEVICE (ORIGINALLY CLEARED DEVICE)

iRhythm Technologies, Inc. Zio AT ECG Monitoring System (K163512)

4. DEVICE DESCRIPTION

The ZEUS System was most recently 510(k) cleared under K163512 as part of the Zio AT ECG Monitoring System ("Zio® AT"). The original cleared ECG monitoring system components consisted of the 1) Zio AT Patch Recorder Device 2) Zio AT Wireless Gateway Device with Bluetooth and Cellular Technology, and 3) ZEUS System for analysis and reporting. This submission discusses the changes made to the ZEUS System only. The ZEUS System is an electrocardiogram (ECG) analysis and reporting software system, designed to process continuously recorded, signal-lead ECG data. The ZEUS System downloads, stores, analyzes and sorts the ECG data to allow iRhythm's Certified Cardiographic Technicians (CCTs) to generate and distribute a report of the findings contained within the data, thereby enabling the provision of a complete ECG processing and analysis service.

The ZEUS System is considered modified as a result of updating its rhythm classification algorithm from a rule and machine-learning implementation to a deep-learning basis. The comparison to the originally cleared device and performance test results demonstrate that the modified ZEUS System is substantially equivalent to the original ZEUS System cleared under K163512, and that the intended use of the device can be consistently fulfilled as originally cleared.

5. INDICATIONS FOR USE

The device is intended to capture, analyze and report symptomatic and asymptomatic cardiac events and continuous electrocardiogram information for long-term monitoring. While continuously recording patient ECG, both patient-triggered and automatically-detected arrhythmia events are transmitted to a monitoring center for reporting. After wear, a final report is generated based on the beat-to-beat information from the entire ECG recording. It is indicated for use on patients 18 years or older who may be asymptomatic or who may suffer from transient symptoms such as palpitations, shortness of breath, dizziness, light-headedness, pre-syncope, syncope, fatigue, or anxiety and patients who are asymptomatic. The reports are provided for review by the intended user to render a diagnosis based on clinical judgment and experience. It is not intended for use on critical care patients.

6. SUBSTANTIAL EQUIVALENCE SUMMARY

The indications for use statement for the modified ZEUS System is an identical reflection of the indications for use as represented in the originally cleared device. The performance testing results demonstrate that the differences in the technological characteristics between the devices do not raise new issues of safety or effectiveness. Therefore, the modified ZEUS System is determined to be substantially equivalent to the original ZEUS System device. A comparison table outlining the differences and similarities between the modified and original ZEUS System is provided in *Table 5.1*.

Table 5.1: Substantial Equivalence Summary Table

Feature/ Function	**Original Device:** Zio AT ECG Monitoring System (K163512)	**Modified Device:** ZEUS System
General Characteristics		
Classification	Class II	Class II
Classification Regulation(s)	21 CFR 870.2800 21 CFR 870.1425 21 CFR 870.2920 21 CFR 870.1025	21 CFR 870.2800 21 CFR 870.1425 21 CFR 870.2920 21 CFR 870.1025
Product Code	DSH, DQK, DXH, DSI	DSH, DQK, DXH, DSI
Patient Environment	Ambulatory	Ambulatory
Patient Population	Non-pediatric, non-critical care patients	Non-pediatric, non-critical care patients
Technological Characteristics		
Data Input	Digital long-term continuous and transmission ECG	Digital long-term continuous and transmission ECG
Data Download	Yes	Yes
Data Storage	Yes	Yes
ECG Analysis	Beat Runs Rhythm Types Heart Rates	Beat Runs Rhythm Types Heart Rates
Rhythm Detection Algorithm	ECGML	ECGML and ECGDL

Feature/ Function	**Original Device:** Zio AT ECG Monitoring System (K163512)	**Modified Device:** ZEUS System
Rhythm Types	- Atrial fibrillation - Complete heart block - Second degree AV block-type II - Pause >3 seconds - Sinus rhythm - Supraventricular tachycardia - Ventricular bigeminy - Ventricular fibrillation - Ventricular tachycardia - Ventricular trigeminy	- Atrial fibrillation - Complete heart block - Second degree AV block-type II - Pause >3 seconds - Sinus rhythm - Supraventricular tachycardia - Ventricular bigeminy - Ventricular fibrillation - Ventricular tachycardia - Ventricular trigeminy - Second degree AV block-type I - Ectopic atrial rhythm - Junctional rhythm - Idioventricular rhythm
Result Integrator	Algorithm Controller	Algorithm Controller, updated to initiate ECG Analysis through ECGDL, and integrate the ECGML and ECGDL labels
Architecture	Integrated Analysis Tool	Integrated Analysis Tool
Platform	PC / Server Mix to Clinician & Patient Websites	PC / Server Mix to Clinician & Patient Websites
QA Tool	Yes	Yes, updated to support the expanded rhythms
Report Output	Yes	Yes
ZEUS Web Services	Store and retrieve the integrated ECGML Labels to ZEUS Database	Store and retrieve the integrated ECGML and ECGDL Labels to ZEUS Database

7. PERFORMANCE DATA

Safety and performance of the modified ZEUS System has been evaluated and verified in accordance with design specifications and applicable performance standards. The modified device's arrhythmia algorithm detection was tested in accordance to *AAMI ANSI EC57: 2012, Testing and Reporting Performance Results of Cardiac Rhythm and ST-Segment Measurement Algorithms*; it was also evaluated according to *60601-2-47:2012*, *Medical Electrical Equipment- Part 2-47: Particular requirements for the basic safety and essential performance of ambulatory electrocardiographic systems*. Additionally, the information presented in this submission has been developed in consideration of the recommendations contained in FDA Guidance documents, *"Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices"* and *"Content of Premarket Submission for Management of Cybersecurity in Medical Devices"*.

The nonclinical verification and performance test results established that the device meets its design requirements and intended use, that the modifications to the originally cleared device do not raise new questions of safety and efficacy. During the development, potential hazards were evaluated and controlled by the risk management activities, including risk analysis, risk mitigation, verification and risk-benefit analysis. The verification and full system-level regression testing demonstrate that the device meets all its specifications.

8. CONCLUSION

Based on the information submitted in this premarket notification, and based on the indications for use, technological characteristics and performance testing comparison to the originally cleared device, the modified ZEUS System raises no new questions of safety and effectiveness and is substantially equivalent to the predicate device.

Exhibit 7

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

June 2, 2017

iRhythm Technologies, Inc.
Rich Laguna
Director of Quality & Regulatory Affairs
650 Townsend Street
Suite 380
San Francisco, CA 94103

Re: K163512
Trade/Device Name: Zio QX ECG Monitoring System
Regulation Number: 21 CFR 870.2800
Regulation Name: Medical Magnetic Tape Recorder
Regulatory Class: Class II
Product Code: DSH, DQK, DXH, DSI
Dated: May 2, 2017
Received: May 3, 2017

Dear Rich Laguna:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in

the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely,

M G Hillebrenner

for Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K163512

Device Name
Zio® QX ECG Monitoring System

Indications for Use *(Describe)*
The Zio QX ECG Monitoring System is intended to capture, analyze and report symptomatic and asymptomatic cardiac events and continuous electrocardiogram (ECG) information for long-term monitoring. While continuously recording patient ECG, both patient-triggered and automatically detected arrhythmia events are transmitted to a monitoring center for reporting. After wear, a final report is generated based on beat-to-beat information from the entire ECG recording. It is indicated for use on patients 18 years or older who may be asymptomatic or who may suffer from transient symptoms such as palpitations, shortness of breath, dizziness, light-headedness, pre-syncope, syncope, fatigue, or anxiety. The reports are provided for review by the intended user to render a diagnosis based on clinical judgment and experience. It is not intended for use on critical care patients.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

510(k) Notification __K163512__

I. GENERAL INFORMATION [21CFR807.92(a)(1)]

Applicant:
iRhythm Technologies, Inc.
650 Townsend Street, Suite 500
San Francisco, CA 94103
U.S.A.
Phone: 415-632-5700
Fax: 415-632-5701

Contact Person:
Rich Laguna
Director Quality & Regulatory Affairs
Phone: 415-632-5749
Email: rlaguna@irhythmtech.com

Date Prepared: May 2, 2017

II. DEVICE INFORMATION [21CFR708.92(a)(2)]

Trade Name:
Zio® QX ECG Monitoring System

Generic/Common Name:
Medical magnetic tape recorder

Classification Names:
Medical magnetic tape recorder [21 CFR§870.2800]
Programmable diagnostic computer [21CFR§870.1425]
Telephone electrocardiograph transmitter and receiver [21CFR§870.2920]
Arrhythmia detector and alarm (including ST-segment measurement and alarm) [21 CFR§870.1025]

Regulatory Class:
Class II (special controls)

Product Codes:
DSH, Recorder, Magnetic Tape, Medical
DQK, Computer, Diagnostic, Programmable
DXH, Transmitters And Receivers, Electrocardiograph, Telephone
DSI, Detector And Alarm, Arrhythmia

III. PREDICATE DEVICES [21CFR708.92(a)(3)]

The following predicate devices have been selected:

- iRhythm Technologies, Inc. Zio® SR ECG Monitoring System [K143513] **(primary)**
- Medtronic, Inc. SEEQ™ Mobile Cardiac Telemetry (MCT) System [K133701]

No reference devices were used in this submission.

IV. DEVICE DESCRIPTION [21CFR708.92(a)(4)]

The Zio® QX ECG Monitoring System consists of three key device components: (1) Zio QX Patch Recorder with Bluetooth technology, (2) Zio QX Wireless Gateway with both Bluetooth and cellular technology, and (3) the Zio ECG Utilization Service (ZEUS) System for data analysis and reporting.

The Zio® QX Patch is a non-sterile, single-patient-use ECG monitor that provides a continuous, single-channel recording in addition to asymptomatic and symptomatic data transmission for up to 14 days. The Zio® QX Patch is applied and activated by the patient. Once activated, the Patch records ECG without patient interaction, with the goal of improving patient compliance via simplicity of operation. The Zio® QX Patch, in conjunction with the Wireless Gateway and the ZEUS System, has arrhythmia auto-detection capabilities. Additionally, patients have the option of pressing a convenient trigger button which marks the continuous record and initiates the wireless transfer of a 90-second ECG strip. The wireless transfer of data is enabled by the Zio® QX Gateway, which requires Bluetooth proximity to the Patch and cellular network reception but no patient interaction to transmit to the monitoring center. The patient is encouraged to document symptomatic events in either the provided booklet, mobile medical app (iOS 9+, Android 4.4+) or via a patient website, which will support symptom-rhythm correlation in the Zio QX Report.

At the conclusion of the wear period (up to 14 days), the patient removes the Zio® QX Patch and returns it by mail to an iRhythm data processing center.

Upon receipt of both symptomatic/asymptomatic transmissions (during wear) and downloaded continuous ECG data (post wear) at iRhythm's Clinical Center (iCC), the data is processed through the ZEUS detection algorithm and delivered to the QA Tool module where the results are reviewed and/or adjusted by iRhythm's Certified Cardiographic Technicians (CCTs) for accuracy. iRhythm employed and trained Patch in-take and CCT personnel follow internal procedures for processing and are made aware of performance limitations and anomalies with both the detection algorithms and software workflow tools. All anomalies are visible to and, where appropriate, are manually corrected by iRhythm Technologies CCTs during the QA review and/or Patch Report edits. The CCT generates a final report (Zio QX Report) of the ECG findings contained within the data, thereby providing a complete ECG processing and analysis service.

Upon explicit request from a clinician responsible for the patient's healthcare, longer segments of ECG data from the continuous recording on the Patch can also be wirelessly

retrieved during the wear period. Alternatively, such periods are also available for inclusion in the final report, where the entire ECG recording is available for review and selective inclusion based on clinical relevance.

V. INDICATIONS FOR USE [21CFR708.92(a)(5)]

The Indications for Use statement for the Zio® QX ECG Monitoring System is as follows:

> The Zio QX ECG Monitoring System is intended to capture, analyze and report symptomatic and asymptomatic cardiac events and continuous electrocardiogram (ECG) information for long-term monitoring. While continuously recording patient ECG, both patient-triggered and automatically detected arrhythmia events are transmitted to a monitoring center for reporting. After wear, a final report is generated based on beat-to-beat information from the entire ECG recording. It is indicated for use on patients 18 years or older who may be asymptomatic or who may suffer from transient symptoms such as palpitations, shortness of breath, dizziness, light-headedness, pre-syncope, syncope, fatigue, or anxiety. The reports are provided for review by the intended user to render a diagnosis based on clinical judgment and experience. It is not intended for use on critical care patients.

The Indications for Use statement for the Zio® QX ECG Monitoring System differs slightly from that of the primary predicate device to address automatically detected events during wear; however, these differences do not alter the intended use of the device. Collectively, the subject device has the same intended use in cardiac arrhythmia diagnostics as the two predicate devices. Differences in the proposed Indications for Use statement are not critical to the intended use of the device, nor do they affect the safety and effectiveness of the subject device relative to the predicate devices. Therefore, the subject device can be considered substantially equivalent to the predicate devices.

VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH PREDICATE DEVICES [21CFR708.92(a)(6)]

The proposed indications for use statement for the Zio® QX ECG Monitoring System reflect the same intended use as represented in the cleared Indications for Use statements for the predicate devices. The performance testing results demonstrate that the differences in the technological characteristics between the devices do not raise any new issues of safety or effectiveness, demonstrating that the subject device is as safe and as effective as the predicate devices. Therefore, the Zio® QX ECG Monitoring System is determined to be substantially equivalent to the predicate devices. A comparison table outlining the differences and similarities between the subject device, the Zio® QX ECG Monitoring System, and the predicate devices is provided in Table 1.

Table 1: Substantial Equivalence Summary Table

Feature	**Subject device:** iRhythm Technologies Zio® QX ECG Monitoring System [K163512]	**Primary predicate:** iRhythm Technologies Zio® SR ECG Monitoring System [K143513]	**Predicate:** Medtronic, Inc. SEEQ™ MCT System [K133701]
General Characteristics			
Classification	Class II	Class II	Class II
Classification Regulation(s)	21CFR§870.2800 21CFR§870.1425 21CFR§870.2920 21CFR§870.1025	21CFR§870.2800 21CFR§870.1425 21CFR§870.2920	21CFR§870.1025
Product Code(s)	DSH, DQK, DXH, DSI	DSH, DQK, DXH	DSI
Patient Environment	Ambulatory	Same	Same
Patient Population	Non-pediatric, non-critical care patients	Same	Non-critical care patients
Technological Characteristics			
Key System Components	1) Zio® QX Patch (wearable sensor) 2) Zio® QX Gateway (transmitter) 3) ZEUS System (software)	1) Zio® SR Patch (wearable sensor) 2) Zio® SR Gateway (transmitter) 3) ZEUS System (software)	1) SEEQ™ MCT Wearable Sensor 2) SEEQ™ MCT Transmitter 3) Software
Event Trigger	Manually by patient or automatically by arrhythmia detection algorithm	Manually by patient	Manually by patient or automatically by arrhythmia detection algorithm

VII. PERFORMANCE DATA [21CFR708.92(b)]

There are no required FDA performance standards for the Zio® QX ECG Monitoring System. All necessary performance testing was conducted on the Zio® QX ECG Monitoring System to ensure performance as intended per specifications and to support a determination of substantial equivalence to the predicate devices.

[21CFR708.92(b)(1)]:
Nonclinical testing included:

- System performance testing
- Mechanical verification testing
- Software verification testing
- Firmware verification testing
- Electrical safety and EMC testing

Automated ECG analysis performance was quantified for any claimed analysis metrics. The resulting statistics demonstrate sensitivity and positive predictivity levels which satisfy requirements.

The scope of the nonclinical testing summarized in Table 2 demonstrates that the Zio® QX ECG Monitoring System is in conformance with FDA-recognized consensus standards and FDA guidance documents.

Table 2: FDA-Recognized Consensus Standards & Guidance Document Summary

FDA #	Body	Number / Version	Title
5-70	AAMI ANSI ISO	14971:2007/(R)2010 (Corrected 4 October 2007)	Medical Devices - Applications Of Risk Management To Medical Devices
19-4	AAMI ANSI	ES60601-1:2005/(R)2012 and A1:2012, C1:2009/(R)2012 and A2:2010/(R)2012	Medical Electrical Equipment - Part 1: General Requirements For Basic Safety And Essential Performance (IEC 60601-1:2005, MOD)
19-12	AAMI ANSI IEC	60601-1-2:2014	Medical Electrical Equipment -- Part 1-2: General Requirements For Basic Safety And Essential Performance -- Collateral Standard: Electromagnetic Disturbances -- Requirements And Tests
19-1	IEC	60601-1-2 Edition 3: 2007-03	Medical Electrical Equipment - Part 1-2: General Requirements For Basic Safety And Essential Performance - Collateral Standard: Electromagnetic Compatibility - Requirements And Tests
19-6	IEC	60601-1-11 Edition 1.0 2010-04 [Including: Technical Corrigendum 1 (2011)]	Medical Electrical Equipment - Part 1-11: General Requirements For Basic Safety And Essential Performance - Collateral Standard: Requirements For Medical Electrical Equipment And Medical Electrical Systems Used In The Home Healthcare Environment
3-127	AAMI ANSI IEC	60601-2-47:2012	Medical Electrical Equipment -- Part 2-47: Particular Requirements For The Basic Safety And Essential Performance Of Ambulatory Electrocardiographic

Table 2: FDA-Recognized Consensus Standards & Guidance Document Summary

FDA #	Body	Number / Version	Title
			Systems
3-52	AAMI ANSI	EC12:2000/(R)2010	Disposable ECG Electrodes
3-118	AAMI ANSI	EC57:2012	Testing And Reporting Performance Results Of Cardiac Rhythm And ST-Segment Measurement Algorithms
N/A	U.S. FDA	October 28, 2003	Guidance for Industry and FDA Staff – Class II Special Controls Guidance Document: Arrhythmia Detector and Alarm
N/A	U.S. FDA	October 2, 2014	Guidance for Industry and FDA Staff – Content of Premarket Submissions for Management of Cybersecurity in Medical Devices

[21CFR708.92(b)(2)]:
No clinical testing was performed in support of this premarket notification.

[21CFR708.92(b)(3)]:
The results confirm by examination and provision of objective evidence that the design output met the design input requirements. The results of the nonclinical testing performed demonstrate that the Zio® QX ECG Monitoring System meets the requirements of established conformance standards and performance specifications necessary for its intended use and does not raise new questions of safety or effectiveness as compared to the predicate devices.

VIII. CONCLUSION

The Zio® QX ECG Monitoring System is substantially equivalent to the predicate devices.

Exhibit 8

U.S. FOOD & DRUG ADMINISTRATION

May 21, 2021

iRhythm Technologies, Inc.
Rey Jacinto
Sr. Manager, Regulatory Affairs
699 8th Street
San Francisco, California 94103

Re: K202359
Trade/Device Name: Zio Monitor
Regulation Number: 21 CFR 870.2800
Regulation Name: Medical Magnetic Tape Recorder
Regulatory Class: Class II
Product Code: DSH, MWJ
Dated: May 20, 2021
Received: May 21, 2021

Dear Rey Jacinto:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal

statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Jennifer W. Shih -S

Jennifer Shih Kozen
Assistant Director
Division of Cardiac Electrophysiology,
Diagnostics and Monitoring Devices
Office of Cardiovascular Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K202359

Device Name
Zio® Monitor

Indications for Use *(Describe)*
The Zio Monitor is a prescription-only, single-patient-use, ECG monitor that continuously records data for up to 14 days. It is indicated for use on patients who may be asymptomatic or who may suffer from transient symptoms such as palpitations, shortness of breath, dizziness, lightheadedness, pre-syncope, syncope, fatigue or anxiety.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

510(k) Notification K202359

I. General Information

Applicant:

iRhythm Technologies, Inc.

699 8th Street, Suite 600

San Francisco, CA 94103 USA

Phone: 415-632-5700

Fax: 415-632-5701

Contact Person:

Rey Jacinto

Sr. Manager, Regulatory Affairs

Phone: 415-214-7440

Email: rey.jacinto@irhythmtech.com

Date Prepared: August 17, 2021

II. Device Information

Trade Name:

Zio® monitor

Generic/Common Name:

Medical magnetic tape recorder

Classification Names:

Medical magnetic tape recorder [21CFR§870.2800]

Regulatory Class:

Class II

Product Codes:

DSH, Recorder, Magnetic Tape, Medical

MWJ, Electrocardiograph, Ambulatory (Without Analysis)

III. Predicate Devices

The following predicate device has been selected:

– iRhythm Technologies, Inc. Zio® XT Patch [K121319]

The following reference device has been selected:
– iRhythm Technologies, Inc. Zio® AT Patch [K181502]

IV. Indications for Use

The Indications for Use statement for the Zio monitor is as follows:

> The Zio monitor is a prescription-only, single-patient-use ECG monitor that continuously records data for up to 14 days. It is indicated for use on patients who may be asymptomatic or who may suffer from transient symptoms such as palpitations, shortness of breath, dizziness, lightheadedness, pre-syncope, syncope, fatigue or anxiety.

V. Device Description

The Zio monitor is a non-sterile, single-patient-use, long-term ambulatory ECG monitor that is adhered to a patient's left pectoral region in a modified Lead II orientation. The goal of the Zio monitor is to help physicians initiate long-term, patient-compliant ECG monitoring utilizing proprietary technology.

The Zio monitor is applied and activated by the patient at home or at a clinic. Once activated, the device provides continuous, uninterrupted ECG recording into memory with minimal patient interaction. There is a button on the surface of the Zio monitor, which serves to activate the device and may be pressed by the patient during wear to indicate when he or she is experiencing a symptom. Additionally, there is a surface LED light that blinks green to confirm proper activation or that the device is working, and orange to indicate loss of connection with the skin or the presence of error conditions.

VI. Comparison of Technological Characteristics with Predicate Devices (Substantial Equivalence)

The Indications for Use statement for the Zio monitor are substantially equivalent to the cleared Indications for Use statement of the predicate device. Differences in the phrasing of the proposed Indications for Use statement from the predicate device are not critical to the intended use of the device, nor do they affect the substantial equivalence of the subject device relative to the predicate device (Section 12.3.2). Therefore, the subject device can be considered substantially equivalent to the predicate device.

The performance testing results demonstrate that the differences in the technological characteristics (i.e. reduced weight and power) between the devices do not raise any

new issues of safety or efficacy as compared to the predicate. Therefore, the Zio monitor is determined to be substantially equivalent to the predicate device.

A comparison table outlining the differences and similarities between the subject device and the predicate device is provided in Table 1.

Table 1. Substantial Equivalence Summary Table

Feature	**Subject Device: Zio® monitor**	**Predicate Device: Zio® XT Patch**
General Characteristics		
Classification	Class II: 21CFR870.2800	Same
Product Code	DSH MWJ	DSH
Patient Environment	Ambulatory	Same
Patient Population	Non-pediatric, non-critical care patients	Same
Technological Characteristics		
Event Trigger	Manually by patient	Same
Size	The Zio Monitor has a reduced form factor	

VII. Performance Data

There are no required FDA performance standards for the Zio monitor. All necessary performance testing was conducted on the Zio monitor to ensure performance as intended per specifications and to support a determination of substantial equivalence to the predicate device.

Nonclinical testing included:

- Mechanical verification testing
- Biocompatibility testing
- Firmware verification testing
- Electrical safety and EMC testing

The scope of the nonclinical testing summarized in Table 2 demonstrates that the Zio monitor is in conformance with FDA recognized consensus standards and FDA guidance documents.

Table 2. FDA-Recognized Consensus Standards & Guidance Document Summary

FDA#	Body	Number / Version	Title
5-40	AAMI ANSI ISO	14971:2012(R)2010 (Corrected 4 October 2017)	Medical Devices – Applications Of Risk Management To Medical Devices
19-4	AAMI ANSI	ES 60601-1:2005/(R)2012 and A1:2012, C1:2009/(R)2012 and A2:2010/(R)2012	Medical Electrical Equipment – Part 1: General Requirements For Basic Safety And Essential Performance (IEC 60601-1:2005, MOD)
19-8	AAMI ANSI IEC	60601-1-2:2014	Medical Electrical Equipment -- Part 1-2: General Requirements for Basic Safety And Essential Performance -- Collateral Standard: Electromagnetic Disturbances -- Requirements And Tests
19-6	IEC	60601-1-11 Edition 1.0 2010-04 [Including: Technical Corrigendum 1 (2011)]	Medical Electrical Equipment – Part 1-11: General Requirements For Basic Safety And Essential Performance – Collateral Standard: Requirements For Medical Electrical Equipment And Medical Electrical Systems Used In The Home Healthcare Environment
3-127	AAMI ANSI IEC	60601-2-47:2012	Medical Electrical Equipment -- Part 2-47: Particular Requirements For The Basic Safety And Essential Performance Of Ambulatory Electrocardiographic Systems
2-220	ISO	10993-1:2009	Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process
2-245	ISO	10993-5:2009	Biological evaluation of medical devices – Part 5: Tests for in vitro cytotoxicity
2-174	ISO	10993-10:2010	Biological evaluation of medical devices – Part 10: Tests for irritation and skin sensitization
13-79	IEC	62304 Edition 1.1 2015-06 CONSOLIDATED VERSION	Medical device software - Software life cycle processes

5-113	ASTM	D7386-16	Standard Practice for Performance Testing of Packages for Single Delivery Systems
5-99	ASTM	D4332-14	Standard Practice for Conditioning Containers, Packages, or Packaging Components for Testing

VIII. Clinical Testing in Support of Substantial Equivalence Determination

No clinical testing was performed in support of this premarket notification.

IX. Conclusion

The results confirm by examination and provision of objective evidence that the design outputs met the design input requirements. The results of the nonclinical testing performed demonstrate that the Zio monitor meets the requirements of established conformance standards and performance specifications necessary for its intended use, and does not raise new questions of safety or effectiveness as compared to the predicate devices. The Zio monitor is substantially equivalent to the predicate device.

Exhibit 9

MD+DI Qmed
MEDICAL DEVICE AND DIAGNOSTIC INDUSTRY

SIGN UP TODAY

CARDIOVASCULAR

Behind the Design: How iRhythm Built Its New Zio Monitor

Miniaturization, usability considerations, and future proofing all informed the design of the company's latest wearable heart monitor.

Amanda Pedersen
October 4, 2023

8 Min Read

IMAGE COURTESY OF IRHYTHM

iRhythm Technologies recently launched its next-generation Zio monitor and enhanced Zio long-term continuous monitoring service in the United States. The San Francisco, CA-based company touts an improved form factor with the new wearable heart monitoring device, which is 23% thinner, 62% lighter, and 72% smaller compared to previous generations of the technology.

But Mark Day, the chief technology officer at iRhythm, told *MD+DI* that the goal in designing the Zio monitor wasn't just to make it smaller, but to deliver a better patient wear experience. Below is a Q&A based on our conversation with Day, in which he explains why the company made these design changes, and how it accomplished it from an engineering perspective. The responses have been edited for length.

MD+DI: What was motivation behind the design considerations for the new Zio monitor?

Day: It's not just about making it smaller, it's about the impact. The journey was really that we took a lot of the information that we've had and feedback from both patients and providers that we've received from the over 6 million Zio XT devices that we've manufactured, distributed, and serviced. And we took a really hard look at how we can improve that experience. So, that was the impetus. It is still, despite its fairly long tenure on the market now approaching the better part of 10 years, it's still an industry-leading diagnostic device with respect to its wear time and patient compliance, but we saw an opportunity to really improve it.

*MD+*DI: What design and engineering challenges had to be overcome to make the device so much smaller and yet still manufacturable?

Day: From a technical viewpoint what we did was really to leverage a lot of advances not just in microprocessor efficiency, which is certainly part of it in terms of miniaturization as well as energy efficiency, but also we really challenged ourselves to figure out how to effectively fit in the smallest possible form factor, which for us was motivated a lot by the size of our battery, which is just a standard, easily available, and fortunately easily recyclable coin cell battery. We challenged ourselves to figure out how to miniaturize the device down to the level of one of those coin cells instead of the two that the Zio XT device uses. And that became feasible by the advances in microelectronic microprocessor efficiency and size as well through its miniaturization. But it also required a lot of really complicated dynamics from an electrical engineering perspective to figure out how to get all the components of a wearable medical device and a biosensor onto that small form factor. So, miniaturization was focused on very clever ways of handling some of the larger components, which for example involved moving some of the big resistors that are required on the device to the more flexible part of the patch instead of on the actual printed circuit board in the housing. And this is a patented feature that we've already received a patent on it and we're pursuing more around it, but it was the idea that these three big resistors are not too big in terms of the homage that they have but also in terms of the size that they are. So, if you put them on the circuit board, they are these pretty big components, so we realized pretty early on that we couldn't really do that and still fit the design constraints. So, we innovated a different way, which was to integrate it into the ECG tracings themselves.

MD+DI: That's really cool. Were there any other design changes or unique features added to this device compared to previous generations?

Day: I'd say we also learned a lot from our experience of how to attach circuit boards to a flexible housing. That was certainly another area that we'd already explored with the Zio XT device but could

yet improve based on the feedback and what we saw both in our manufacturing as well as our intake experience from the device.

But the other thing is to really talk more about the adhesive structure, which we call the dermal adhesive assembly. It's really the part of the patch that secures itself to the patient, which is obviously critical. For that it wasn't so much that we went back and reimagined a different adhesive, we do value the place that we've gone, which is the custom adhesive formulation. And we still have a lot of trust and belief that is effectively an appropriately balanced approach where you kind of have to have an aggressive enough adhesive to be able to work well, but not so aggressive that it's uncomfortable or irritating to a meaningful portion of population. So, it wasn't so much on the adhesive itself but rather on our observation that over time certainly one of the things that we've seen is that when patients sweat ... that sweat gets absorbed in the hydrocolloid adhesive, and one component of that adhesive in particular. And normally, like on the Zio XT patch, which is basically a fixed surface, it doesn't really have anywhere to go. So, it goes into the adhesive, and it changes the structure of the adhesive a little bit, and it has to basically get reabsorbed in the skin, which it will do if the patient stops sweating over time, but that's not necessarily an ideal approach.

So, we put perforations in the dermal adhesive assembly itself to allow that moisture to transpire in one direction to be able to handle that moisture creation more efficiently and frankly, from a performance perspective, more effectively, and more comfortably from a patient's perspective, which is that you don't have this kind of moist mass against you for a long period of time, it figures out how to kind of passively get the moisture away from the skin. And we think all of that is going to result in a more comfortable experience for the patient.

MD+DI: I noticed the press release about the Zio monitor launch mentioned the device has a waterproof housing, but then in the footnotes it basically said that doesn't mean the device should be submerged in water, so patients still have to be careful if they're in a bathtub or whatnot.

Day: In general, water and adhesives don't mix very well together. But the main reason [the device shouldn't be submerged in water] is because water conducts electricity, so it will actually short the electrodes when you are swimming or you otherwise submerge it, you will also impact the performance over time. You can do those things, but we don't recommend them, you won't get any ECG that's readable of that. And it can't do good things to the adhesive, it will probably shorten your wear time.

MD+DI: What other unique takeaways or design and engineering lessons can you take from this project that you might be able to apply to a future project?

Day: The other lesson that we put into this as well was to prepare for the future, in a lot of ways. In the time frame of the Zio XT device being commercialized we also introduced the Zio AT device, which looks similar to the Zio XT device (same form factor and size) but underneath the hood, the circuit board underneath that device between those two devices is different, one having Bluetooth the other not.

And really, as we look forward to what we think the future looks like for biosensors of all kinds is that they have a connected feature in them. And we'll have to work through the appropriate regulatory and reimbursement processes to see this fully change, but I would strongly suspect that in five to 10 years the idea of a wearable device that doesn't communicate with some type of back-end infrastructure during, say, a wear time of a cardiac arrhythmia patient, will not be competitive.

...All of this gets put into the engineering consideration of effectively looking at the landscape around you and trying to figure out what kind of technology you need to put into a hardware platform, because you don't want to be changing your hardware platform continuously, it's extremely costly for a business to invest in a new hardware platform ... So, you want to take an approach of making sure that you can design and develop a circuit board and frankly, an entire platform, that is future proof from the perspective of being connectable not just to our own infrastructure of say a gateway, a cellular gateway, but also a patient’s phone. That just opens up all kinds of possibilities and optionality of the platform in the future so, we really designed this to not just perform well from a patients perspective, but also to enable this platform to be a true platform in the sense that the Zio monitor device that we just introduced and we're rolling out right now is really the first of a number of different device services, effectively, that we deliver off this platform.

About the Author

Amanda Pedersen

Amanda Pedersen is a veteran journalist and award-winning columnist with a passion for helping medical device professionals connect the dots between the medtech news of the day and the bigger picture. She has been covering the medtech industry since 2006.

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Exhibit 10

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2122
JACC March 7, 2023
Volume 81, Issue 8, suppl A

Spotlight on Special Topics

INITIAL REAL WORLD AND CLINICAL EXPERIENCE OF THE NEXT GENERATION AMBULATORY ECG ZIO MONITOR: IMPLICATIONS FOR STANDARD AND EXTENDED WEAR MONITORING

Moderated Poster Contributions
Pulmonary Vascular Disease, Valvular Heart Disease, Special Topics Moderated Poster Theater 4_Hall F
Saturday, March 4, 2023, 1:30 p.m.-1:40 p.m.

Session Title: Innovation, Digital Health, and Technology Moderated Poster Session 1
Abstract Category: 60. Spotlight on Special Topics: Innovation, Digital Health, and Technology
Presentation Number: 1021-07

Authors: Jay H. Alexander, Mike Hsu, Jeffrey Ellis, ADINA MURESAN, Charlotte Bame, Alan Wilk, Lori Crosson, Kevin Clarkson, Mark Day, Mintu Turakhia, Judith C. Lenane, Highland Park Hospital, Bannockburn, IL, USA, iRhythm Technologies, Inc, San Francisco, CA, USA

Background: Bulky ambulatory ECG devices may result in reduced patient compliance; subsequent missing and/or incomplete data complicate clinical decision making. A lighter and more compliant next generation ECG monitor (Zio monitor; iRhythm Technologies Inc; San Francisco, CA) cleared by FDA in May 2021 has been launched to improve patient and provider experience. This report details the first wear and clinical experience of the monitor.

Methods: Commercial data were analyzed from 673 monitors prescribed by 75 US physicians. Wear metrics, analyzable data and clinical findings were determined. Additionally, 30 subjects enrolled in an IRB-approved, extended-wear validation study of safety and feasibility of 30-day wear.

Results: Zio monitors demonstrated high compliance and high quality ECG. Wear metrics and analyzable ECG were compared to national Zio XT prescriptions (Fig 1). Arrhythmia yield (AF ≥30 sec, SVT ≥90 bpm & ≥4 bt, VT ≥100 bpm & ≥4 bt, inc PVT/TdP/VF, Pause ≥3 s, and/or AVB (any 2nd Deg or CHB)) was 77.1% for Zio XT and 80.9% (p=0.0168) for Zio monitor.

30-day clinical data demonstrated high compliance and high analyzable ECG (Fig 1) with no clinically significant skin irritation. Extended wear monitoring yielded additional clinical findings beyond 14 days.

Conclusion: Post-clearance evaluations of this next generation ECG monitor showed consistent and even improved performance, with potential to greatly improve monitoring and decision making in complex patients.

	Standard Zio XT Commercial (n=262,287)	Next Gen Zio Monitor Commercial (n=673)	Extended Wear Monitor Clinical Study (n=30)
Prescribed Wear	14 days	14 days	30 days
Mean Wear	11.7 ± 3.6 days	12.6 ± 2.7 days	24.9 ± 9.3 days
Median Wear	13.7 days	13.9 days	29.0 days
Mean/Median Analyzable ECG	95.4% / 98.7%	97.1% / 98.9%	99.3% / 100%
Dimensions / Weight	132 x 51 x 14mm 24.5g	139.7 x 55.8 x 10.6mm 10g	

Comparison of Zio Monitor and Zio XT. Analyzable ECG and wear measures were from Zio Monitors prescribed 5/10/22 to 9/9/22 compared to Zio XT prescribed 5/10/22 to 9/9/22 nationally. Dimensions and weight of devices are compared. Mean wear durations: p<0.0001 For Next Gen vs Zio XT; p<0.0001 for Extended Wear vs Next Gen; p<0.0001 for Extended Wear vs Zio XT.

Exhibit 11

ZIO®

Instructions for Use

Read this booklet to learn more about using your Zio monitor.

Apply your Zio monitor immediately and do not throw away this booklet.

MyZio app

Use the MyZio app to log symptoms, track progress, access information about your Zio monitor, and view helpful video tutorials

Scan QR code to download

1. Open the camera app on your phone.
2. Hold the camera so you can see the QR code on your screen.

   A notification should appear in your camera app.
3. Tap the notification to download the app.

We are here to support you

- Contact Customer Care at (888) 693-2401
- Customer Care is available 24 hours a day/7 days a week to answer questions about your Zio monitor.
- Customer Care troubleshoots issues with you and reminds you to return your Zio monitor.
- Customer Care collects your feedback about the Zio monitor.

Contents

Visit iRhythm's website **www.irhythmtech.com/user-manuals** to view and download documents pertinent to privacy notices, product warranty, terms of service, and other product information, including additional copies of user manuals.

Welcome to Zio monitor

Product Description

The Zio® ECG Monitoring System is an ambulatory Electrocardiogram (ECG) monitoring system. The Zio ECG Monitoring System consists of two components:

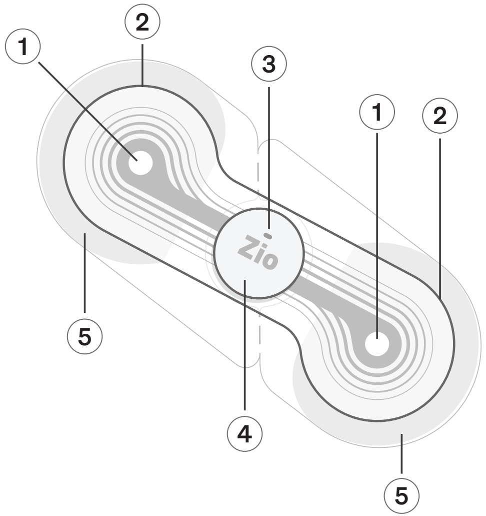
(1) Zio monitor

(2) proprietary algorithm software.

The Zio monitor is a single-use ECG monitor that provides a continuous, single-channel recording for up to 14 days. The Zio monitor records ECG data without patient interaction, with the goal of improving patient compliance via simplicity of operation. Patients have the option of pressing a convenient button and filling out a log to document symptomatic events, which will support symptom-rhythm correlation in the diagnostic report.

After conclusion of the wear period (up to 14 days), the patient removes the Zio monitor and returns it by mail to iRhythm for processing. After receipt, the data is analyzed by iRhythm's proprietary algorithm before a Certified Cardiographic Technician (CCT) reviews the results and generates a report of the key findings.

Example of Zio monitor



1. Electrode – acquires ECG data
2. Adhesive wings – adheres the Zio monitor to the upper-left chest
3. Light – momentarily flashes green when activated and orange in the event of an error.

   After activation, you will not see any lights.

   Refer to Troubleshooting - flashing lights on page 17.
4. Zio button – activates the Zio monitor. The patient presses this button when a symptom is felt.
5. Clear plastic backings – remove from back of Zio monitor and discard before applying to the chest.

Package contents

Note: The patient must keep the device box until the end of the prescribed wear period. The postage-paid box is re-used to return the device and Symptom Log to iRhythm.

Instructions for Use, quantity 1

Symptom Log, quantity 1

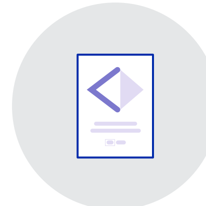
Zio monitor, quantity 1

Note: The Zio monitor is within a pouch

Prep Materials box, quantity 1

Postage-paid return box (same as device box)

The patient must keep this box. The Zio monitor is returned in the box at the end of the prescribed wear period.



Adhesive remover wipes, quantity 2

Note: The adhesive remover wipes are in the Instructions for Use.

The Prep Materials box is within the device box and contains the following items for skin preparation:

Disposable razor, quantity 1

Exfoliator disc, quantity 1

Alcohol wipe, quantity 2

Getting started

The Zio monitor is an ECG monitor that continuously records the electrical activity of the heart. It is intended to be worn continuously for a time period specified by a provider for up to 14 days.
Each patient's wear duration may differ due to individual wear experiences. Excessive sweating may decrease wear duration.

In-clinic:

Register the patient

1. Register the patient online at www.ziosuite.com.
2. Remove the following items from the device box:
   - Pouch with Zio monitor
   - Prep Materials box
   - Symptom Log
3. Instruct the patient to keep the box. The box is used to return the device at the end of the prescribed wear period.
4. On the cover of the Symptom Log, write the patient's name, start date, and prescribed wear duration.

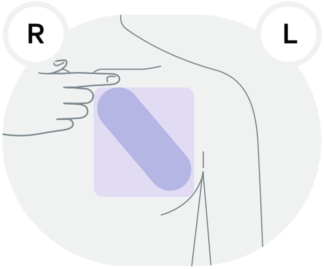
   The patient writes the date on the cover when they remove the Zio monitor for return.

At home:

1. Remove the following items from the device box:
   - Pouch with Zio monitor
   - Prep Materials box
   - Symptom Log
2. Keep the box. The box is used to return the device at the end of the prescribed wear period.
3. On the cover of the Symptom Log, write your name and start date.
4. Refer to your welcome letter and write the number of days on the cover prescribed by your physician for wearing this Zio monitor.
5. Do not write the removal date until you remove the Zio monitor for return at the end of your prescribed wear period.

1. Position prep area

Remove the razor, exfoliator, and alcohol wipe from the prep materials box.



In-clinic:

1. Request the patient stand with their arms relaxed by their sides during the Zio monitor application. If standing is not possible, the patient may sit upright.
2. Locate the area on the patient's upper-left chest one finger width below the left collarbone from the center of the chest.

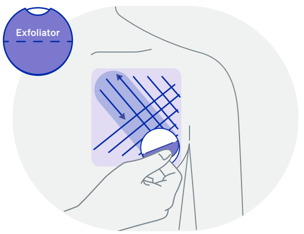
   The Zio monitor will be placed diagonally on the chest after the skin is prepared.

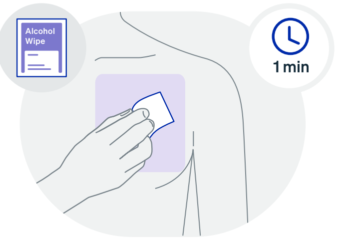
At home:

1. Make sure your chest is visible and clear in front of a mirror.
2. Find the area on your upper-left chest one finger width below the left collarbone from the center of the chest.

   The Zio monitor will be placed diagonally on the chest after the skin is prepared.

2. Prep skin





1. Shave chest area requiring skin preparation (all genders, including those with no visible hair).

a. Hold the protective cover on the razor and pull the razor from the cover.

b. Shave the entire area with the razor. **Shaving is necessary whether hair is visible or not visible.**

c. Ensure the skin is fully clean and dry before you continue.

2. Exfoliate prep area:

a. Lift up the plastic tab on the exfoliator to use as a handle.

b. Gently exfoliate the entire area with the rough side of the exfoliator

c. Focus on the top and bottom corners; complete 40 strokes in total: both diagonal directions, up and down, and side to side.
Exfoliating may cause expected skin redness.

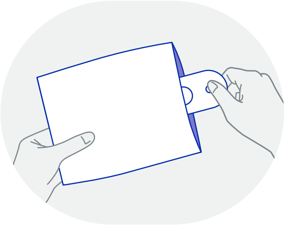
3. Clean and let dry:

a. Use an alcohol wipe to clean the prepared chest area.

Cleaning may cause a slight tingling sensation.

b. Let the skin dry for at least 1 minute for proper adhesion.

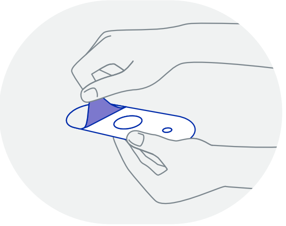
3. Apply Zio monitor



1. Open the Zio monitor pouch:

a. Tear open from either notch.

b. Remove the Zio monitor.



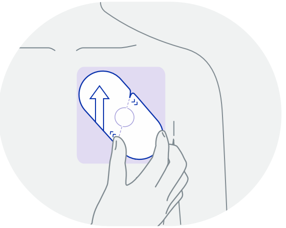
2. Peel clear backings:

a. Hold the middle of the Zio monitor.

b. Pull off the clear plastic backings carefully and avoid touching the exposed adhesive.

c. Keep the paper tabs intact on the other side of the monitor.

Note: Wait to remove the paper tabs in Step 5.



3. Apply the Zio monitor:

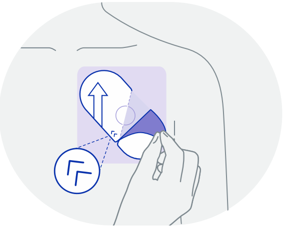
a. Ensure the white arrow on the paper tab is pointing upward.

b. Place the Zio monitor diagonally on the prepared skin area, one finger width below the left collarbone from the center of the upper-left chest.

4. Massage paper tabs:

a. Massage the paper tabs on the wings of the Zio monitor firmly for 2 minutes to fully adhere the Zio monitor to the chest.

b. Do not move or remove the Zio monitor after applying it to the chest.



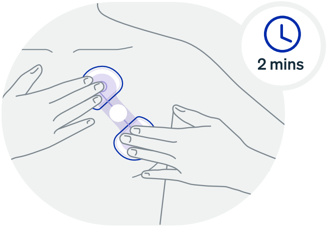
5. Remove paper tabs:

a. Find the double arrows located above and below the center of the Zio monitor.

b. Peel the tab in the direction of the double arrows. Ensure the adhesive wing does not lift using your other hand.

The center of the Zio monitor may slightly lift from the skin as the tab is peeled.

c. Remove the remaining tab.



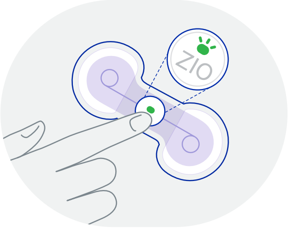
6. Massage wings again:

a. Massage the adhesive wings firmly onto the skin for another 2 minutes to prevent the Zio monitor from slipping or falling off the chest.

b. If remnants of the paper tab are on the wings, peel outward from the center of the monitor.

c. Do not move or remove the Zio monitor after applying it to the chest.

4. Activate Zio monitor



- **Press and release button:**
  a. Press and quickly release the button on the Zio monitor.
  b. Watch the light briefly flash green to indicate the Zio monitor is recording ECG data.
  c. If you do not see a green light, call Customer Care at (888) 693-2401.
  d. Retrieve the Symptom Log and write the "Start Time" on the cover.

Wearing Zio monitor

During the first 24 hours, avoid the following activities:

Do not swim or take a shower/bath

Avoid activities that may cause you to sweat

Do not submerge your Zio monitor in water (pool, hot tub, bath)

Do not apply soap or lotions near your Zio monitor

After the first 24 hours, you can continue normal activities:

Take brief showers with your back to the water

Light exercise is acceptable but avoid excess sweating (intense exercise, sauna)

Do not submerge your Zio monitor in water (pool, hot tub, bath)

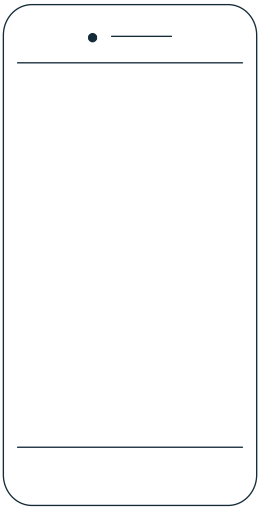
Do not apply soap or lotions near your Zio monitor

In-clinic: review with your patient

- Ensure the patient understands the purpose and importance of the Zio ECG monitoring system.
- While towel drying after a shower, the patient should hold the Zio monitor with one hand.
- Review how to log symptoms with the patient. Refer to Logging symptoms on page 15.

MyZio app

Use the MyZio app to log symptoms, track progress, access information about your Zio monitor, and view helpful video tutorials.



Scan QR code to download the app

1. Open the camera app on your phone.
2. Hold the camera so you can see the QR code on your screen. A notification should appear in your camera app.
3. Tap on the notification to download the app.

Logging symptoms

Logging symptoms provides the healthcare provider with additional information to help analyze the patient's health condition and develop a plan of care. Not all patients experience symptoms.

A "symptom" is anything unusual the patient feels or experiences.

1. Press the button on your Zio monitor when you feel a symptom.

- The light does not flash when the button is pressed.
- If you forget to either press the button or log a symptom, the Zio monitor is recording the ECG data.

2. Log the symptom in either the MyZio app or in the Symptom Log with the following information:

- Date and time the button was pressed.
- Symptom and length of time the symptom was felt or experienced.

  Note: If the reason for the button press is not listed, select "Other" and describe the symptom.
- Activity when the symptom was experienced. (for example, walking the dog, sleeping, standing after sitting)
- If all pages in the Symptom Log are used, download the MyZio app and continue logging symptoms.

Types of symptoms

Chest pain
Discomfort, tightness, or pressure in the chest area

Racing
Heart is pounding or beating too fast

Fainted
Passed out or lost consciousness

Short of breath
Difficulty breathing or unable to catch breath

Irregular beats
Heart is skipping beats or beating out of its normal rhythm

Other
Select and write the reason for button press, if not listed

Lightheaded
Dizzy and/or slightly faint

Any writing outside of the requested entries on the Symptom Log or on any materials included with the device will not be documented or shared.

Contact your physician to share additional information with them.
If you have questions or concerns about your Zio monitor, visit https://www.irhythmtech.com/patients/myzio

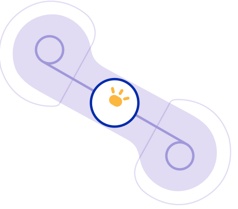
Troubleshooting – flashing lights

You will not see any lights or hear any sounds when your Zio monitor is functioning properly.

If an orange light is rapidly flashing (3 flashes per second):

- This indicates your Zio monitor is not working.
- Call Customer Care at (888) 693-2401.

If an orange light is slowly flashing:



- This indicates your Zio monitor is not well attached to your skin. It does not mean something is wrong with your heart.
- Massage the adhesive wings for 3-5 minutes until the orange light disappears to secure your Zio monitor to your skin.
- If flashing persists or reoccurs, call Customer Care at (888) 693-2401.

Troubleshooting – general

My Zio monitor fell off. What should I do?

If your Zio monitor has fallen off, call Customer Care at (888) 693-2401.

Can I travel while wearing my Zio monitor?

Yes. If you are questioned about your Zio monitor, show the Security Screening Statement also found in your Symptom Log or in the MyZio app.

This person is wearing an iRhythm Zio monitor prescribed by their provider. This device is currently adhered to the patient's chest, where it is monitoring their heart. It can only be removed under the direction of their provider.

If you have any questions, please contact the iRhythm Customer Care.

Can I ship with UPS or FedEx to return my Zio monitor?

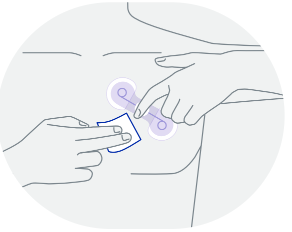
If you decide not to return your Zio monitor with USPS, please send back your Zio monitor via expedited shipping (FedEx, UPS) at your own expense.

Send it to the following address:

iRhythm Technologies
Three Parkway North, Suite 400
Deerfield, Illinois 60015

Removing Zio monitor

At the end of your prescribed wear time, open the adhesive remover and follow steps below to peel off your Zio monitor



1. Gently lift the center of your Zio monitor up.
2. Starting from the center, use the adhesive remover to wipe the area between your skin and your Zio monitor.
3. Continue to wipe as you peel off your Zio monitor, one side at a time.
4. Keep your Zio monitor aside for return and refer to step 2 on page 20 for further instructions.
5. Finally, wash your skin with mild soap, rinse with water, and pat dry.

It is expected for your skin to feel slightly irritated after removing your Zio monitor.

It is expected for your Zio monitor to flash orange as you remove it.

Returning Zio monitor

1. Complete your Symptom Log & survey

- On the cover of the Symptom Log, fill in the date the Zio monitor was removed.
- Fill out the survey in your Symptom Log to tell us about your experience. If you prefer to give your feedback online, go to www.ziopatient.com

2. Package your Zio monitor & Symptom Log

- Adhere your Zio monitor to the inside bottom of the Zio monitor box and place the Symptom Log on top.
- Seal the box by peeling the tape off the front of the box and press firmly on the flap to close.
- It is okay to mail your Zio monitor if it's still flashing orange.

3. Mail your Zio monitor

- Drop the Zio monitor box inside any USPS mailbox or take it to a post office.
- You can also schedule a free USPS pickup at www.ziopickup.com.
- Mail your Zio monitor back promptly so your healthcare provider can share the results with you as soon as possible.

Technical references

Patient identification

Before placing your Zio monitor in the Zio monitor box, please write your name on the line above the return address. By writing your name on the return label, you are providing another method of identification for your Zio monitor and are consenting to the potential viewing of your name on the return label. You may choose to not write your name on the return label.

Notification of privacy practices

As participants in your health care, we are required by applicable federal and state law to maintain the privacy of your Protected Health Information (PHI).

Our full Notice of Privacy Practices, found at www.irhythmtech.com, describes our privacy practices, our legal duties, and your rights concerning your PHI.

Intended use

The Zio monitor is intended to capture symptomatic and asymptomatic cardiac events in a continuous electrocardiogram record for long-term monitoring.

Indications for use

The Zio monitor is a prescription-only, single-use ECG monitor that continuously records data for up to 14 days. It is indicated for use on patients who may be asymptomatic or who may suffer from transient symptoms such as palpitations, shortness of breath, dizziness, lightheadedness, pre-syncope, syncope, fatigue, or anxiety.

Contraindications

- Do not use the Zio monitor for patients with symptomatic episodes where instance variations in cardiac performance could result in immediate danger to the patient or when real-time or in-patient monitoring should be prescribed.
- Do not use the Zio monitor in combination with external cardiac defibrillators or high frequency surgical equipment, near strong magnetic fields or devices such as MRI.
- Do not use the Zio monitor on patients with a neurostimulator, as it may disrupt the quality of ECG data.
- Do not use the Zio monitor on patients who do not have the competency to wear the device for the prescribed wear period.

Safety Information

CAUTION: Federal (U.S.A.) law restricts the sale of this device to or on the order of a physician.

Warnings

- Do not use the Zio monitor on patients with known allergic reaction to adhesives or hydrogels or with family history of adhesive skin allergies. If allergic symptoms, severe skin irritation, or signs of skin infection develop, remove the device from the patient's chest and discontinue wear. Reaction to adhesives may include severe redness and itching, hives, and blisters. Contact your healthcare provider and Customer Care to report the reaction.
- The Zio monitor is MR unsafe.

  Do not expose the Zio monitor to a magnetic resonance (MR) environment.
  - The MR magnet core can attract the ferromagnetic materials in the Zio monitor, creating a risk of projectile injury to the patient and others in proximity of the Zio monitor and MR device.
  - Metal components in the Zio monitor can heat during MR scanning, resulting in the potential for thermal injury and burns.
- Do not use the Zio monitor on patients with broken skin. Only apply to intact skin.
- Do not reuse the Zio monitor on the same patient or on multiple patients. It is a single-use device. Reuse of the device may result in mixed patient results, poor adhesion, and poor ECG signal.
- Do not modify this equipment without authorization of the manufacturer.

Precautions

- During storage and prior to prescription for a patient, do not exceed the temperature and humidity limitations for the Zio monitor. Devices exposed to environmental conditions outside the specified range may have degraded adhesive and battery performance.
- Observe the temperature and humidity specifications for transportation and storage listed on the box and in the instructions for use.
- Confirm the expiration date for the Zio monitor listed on the Zio box or pouch. Use of an expired device may cause a degradation of ECG signal quality and a low battery condition. Apply the device on or before expiration date.
- Recorded ECG data cannot be retrieved for analysis unless you return your Zio monitor. Keep the original Zio monitor box. The box is designed to protect the Zio monitor and Symptom Log in the return mail when properly sealed. Follow the return instructions in this manual. If the box is damaged during opening or handling or lost, contact Customer Care.
- Safety and effectiveness of the Zio monitor on pediatric patients (younger than 18 years old) has not been established.
- Do not use the Zio monitor on patients receiving any form of pacing therapy. Paced cardiac rhythms may not be accurately detected leading to incorrect preliminary findings.

- Carefully prepare skin on the patient's upper left chest prior to applying the Zio monitor. Observe the instructions for proper shaving, exfoliating, and cleaning. Proper placement and alignment of the Zio monitor on the patient's chest is important for recording ECG data. Carefully follow the sequence of all steps in the application instructions to ensure the device is properly positioned and securely adhered to the patient's chest.
- Avoid delays in recording ECG data. After applying the Zio monitor to the patient's chest, follow the instructions in this manual to activate recording of ECG data. If the light on the Zio monitor does not flash green after a second activation attempt, contact Customer Care.
- Exposing the Zio monitor to any sources of infrared light, such as direct sunlight, can disrupt the recording of ECG data. Wear clothing if exposure to infrared light, such as direct sunlight, cannot be avoided.
- If the patient has a known allergic reaction to limonene, the active ingredient in the adhesive remover, use baby oil or petroleum jelly to aid removal instead of the adhesive remover wipe.

Serious incident reporting

If you become aware of any malfunction of our device which has resulted or could result in serious health consequences for the user, patient, or any other person, please inform us immediately and inform the Competent Authority of your country.

Symbols glossary

SYMBOL	SYMBOL TITLE	DESCRIPTION/ EXPLANATION
	Manufacturer	Indicates the medical device manufacturer
QTY:	Net quantity of contents	Net quantity of contents
	Do not use if package is damaged	Indicates a medical device should not be used if the package has been damaged or opened and that the user should consult the instructions for use for additional information
	Use-by date	Indicates the date after which the medical device is not to be used
LOT	Batch code	Indicates the manufacturer's batch code so that the batch or lot can be identified
REF	Catalogue number	Indicates the manufacturer's catalogue number so that the medical device can be identified
SN	Serial number	Indicates the manufacturer's serial number so that a specific medical device can be identified
UDI	Unique device identifier	Indicates a carrier that contains unique device identifier information
	Temperature limit	Indicates the temperature limits to which the medical device can be safely exposed
	Humidity limitation	Indicates the range of humidity to which the medical device can be safely exposed
	Do not reuse	Indicates a medical device that is intended for one use, or for use on a single patient during a single procedure
	Consult instructions for use	Indicates a medical device that is intended for one use, or for use on a single patient during a single procedure

SYMBOL	SYMBOL TITLE	DESCRIPTION/ EXPLANATION
	Caution	Indicates the need for the user to consult the instructions for use for important cautionary information such as warnings and precautions that cannot, for a variety of reasons, be presented on the medical device itself
	Type BF applied part	To identify a type BF applied part complying with IEC 60601-1. A Type BF Applied Part includes a patient connection that is intended to deliver electrical energy or an electrophysiological signal to or from the patient
	Magnetic Resonance (MR) unsafe	A medical device which poses unacceptable risks to the patient, medical staff, or other persons within the MR environment
	Separate collection	To indicate that the product shall be separated when disposed
IP27	Degrees of protection provided by enclosure	Protected against solid foreign objects of 12.5 mm diameter and greater, and protected against the effects of temporary immersion in water
	FCC compliant radio frequency equipment	Indicates compliance with the Federal Communications Commission (FCC) rules in the United States of America The FCC identifier (ID) includes the grantee code and product code.
Rx ONLY	Prescription only	Requires prescription in the United States of America

Device specification

The Zio monitor is not manufactured with natural rubber latex.

Performance characteristics

ECG channels	1 channel
Memory capacity	> 14 days
Recording format	Continuous
Service life	Up to 14 days
Shelf life	6 months

Electrical characteristics

Medical equipment type	BF Applied Part
ECG frequency response	0.67 Hz to 40 Hz
ECG input impedance	> 10 MΩ
ECG differential range	± 1.65 mV
ECG A/D sampling rate	200 Hz
ECG resolution	15.5 bits
Gain accuracy	Maximum amplitude error +/- 10%
Gain stability	< 3% over a 24-hour period
Timing accuracy	< 30 sec over 14-day wear period

Power specifications

Battery type	1 lithium manganese dioxide coin cell
Battery life	> 14 days

Physical characteristics

Dimensions	5.5 × 2.2 × 0.4 in 139.7 × 55.8 × 10.6 mm
Weight	10 g

Environmental specifications

Operational temperature	41 to 104° F | 5 to 40° C
Operational altitude	-1,000 to 10,000 ft | -305 to 3,048 m
Shipping (short-term storage) temperature	-4 to 104° F | -20 to 40° C
Long-term storage temperature	64 to 80° F | 18 to 27° C
Operational and storage humidity	10% to 95% (non-condensing)
Storage altitude	-1,000 to 14,000 ft | -305 to 4,267 m

Essential performance

The Zio monitor continuously records ECG data during wear. After wear, the device is returned, and the complete ECG recording is extracted for analysis. If the device cannot record as intended, the Zio monitor alerts the patient that functionality is impaired. Risks associated with failure of the devices to perform as intended have been mitigated to an acceptable level.

Electrical Safety and Compatibility

- WARNING: The Zio monitor should not be used adjacent to or stacked with other equipment.
- WARNING: Portable and mobile RF communications equipment can affect medical electrical equipment. Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the Zio monitor. Otherwise, degradation of the performance of this equipment could result.
- CAUTION: The Zio monitor needs special precautions regarding EMC and needs to be utilized according to the EMC information provided in the following tables.

The Zio monitor was tested for electromagnetic compatibility (EMC) according to the International Electrotechnical Commission (IEC) 60601-1-2 standard.

The Zio monitor meets the requirements of the standard and is suitable for a home healthcare environment.

Table 1: Manufacturer's declaration — electromagnetic emissions	
Emissions test	**Compliance**
RF emissions CISPR 11	Group 1
RF emissions CISPR 11	Class B
Harmonic emissions IEC 61000-3-2	Not applicable
Voltage fluctuations/flicker emissions IEC 61000-3-3	Not applicable

Table 2: Manufacturer's declaration — electromagnetic immunity		
Immunity test	**IEC 60601 test level**	**Compliance level**
Electrostatic Discharge (ESD) IEC 61000-4-2	±8 kV contact ±15 kV air	±8 kV contact ±15 kV air
Power frequency (50/60 Hz) Magnetic field IEC 61000-4-8	30 A/m	30 A/m
Proximity magnetic field IEC 61000 4-39	8 A/m 30 kHz 65 A/m 134.2 kHz 2.1 kHz Pulse 7.5 A/m 13.56 MHz 50 kHz Pulse	8 A/m 65 A/m 7.5 A/m

Table 3: Manufacturer's declaration — electromagnetic immunity		
Immunity test	**IEC 60601 test level**	**Compliance level**
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz outside ISM bands	3 Vrms
	10 Vrms 150 kHz to 80 MHz in ISM bands	10 Vrms

Table 4: Manufacturer's declaration — electromagnetic immunity		
Immunity test	**IEC 60601 test level**	**Compliance level**
Radiated RF IEC 61000-4-3	10 V/m 80 MHz to 2.7 GHz	10 V/m
	28 V/m 385, 450, 810, 870, 930 MHz 18 Hz pulse	28 V/m
	9 V/m 710, 745, 780 MHz 217 Hz pulse	9 V/m
	28 V/m 1720, 1845, 1970, 2450 MHz 217 Hz pulse	28 V/m
	9 V/m 5240, 5500, 5783 MHz 217 Hz pulse	9 V/m

Federal Communications Commission (FCC) Compliance

This system complies with part 15 of the FCC Rules. Operation is subject to the following two conditions: (1) this system may not cause harmful interference, and (2) this system must accept any interference received, including interference that may cause undesired operation.

ZIO® BY iRHYTHM

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(888) 693-2401 | www.irhythmtech.com
 | Date of first issue: 2024-10

LB10117.01

Exhibit 12

TELEHEALTH & HOME ENROLLMENT WITH ZIO

Remote cardiac monitoring is simple with Zio.

Zio fits into telehealth workflows easily, and ensures your patients can get access to care without an office visit.

Reduce Covid-19 exposure with Home Enrollment.

Home Enrollment allows patients to receive and apply their single-patient-use Zio monitor at home, rather than the clinic. This provides three key benefits:

1

Reduces patient and staff exposure by eliminating

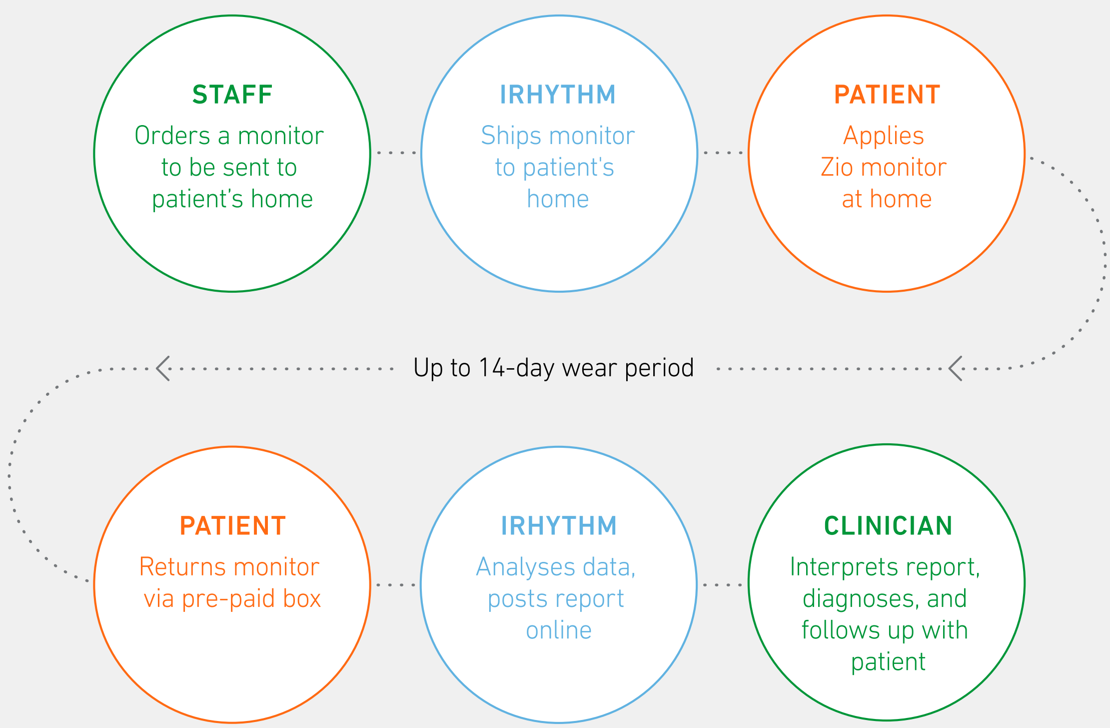
2

Eliminates need for cleaning or re-using

3

Ensures that patients continue to receive access to necessary cardiac monitoring.

How does it work?

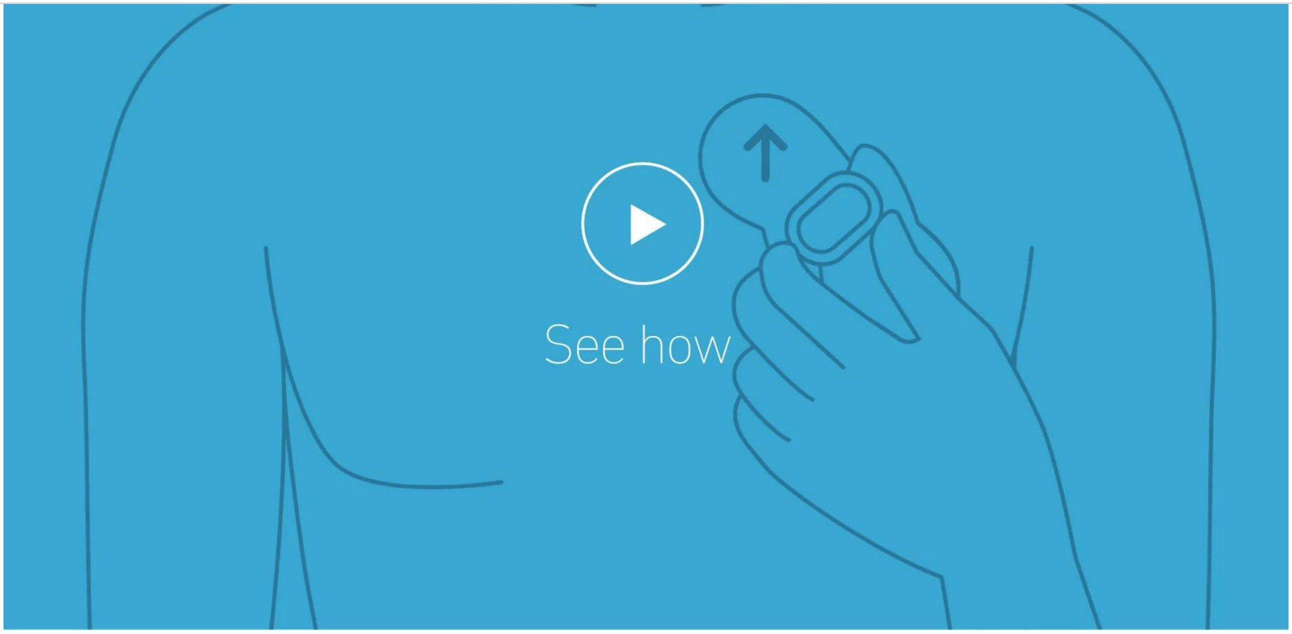


Home Enrollment patient compliance and performance on par with in-clinic application

	DEVICES APPLIED IN CLINIC	APPLIED BY PATIENTS AT HOME
Mean wear duration (days)	12.5	12.1
Median wear duration (days)	13.8	13.7
Mean analyzable time	95.1%	95.4%
Median analyzable time	98.4%	98.4%
Mean age	75.2	74.3
Median age	74.0	73.0

Data on file. Zio XT monitors prescribed for 14-day wear for age 65+. (Zio Database, iRhythm Technologies. 2019)

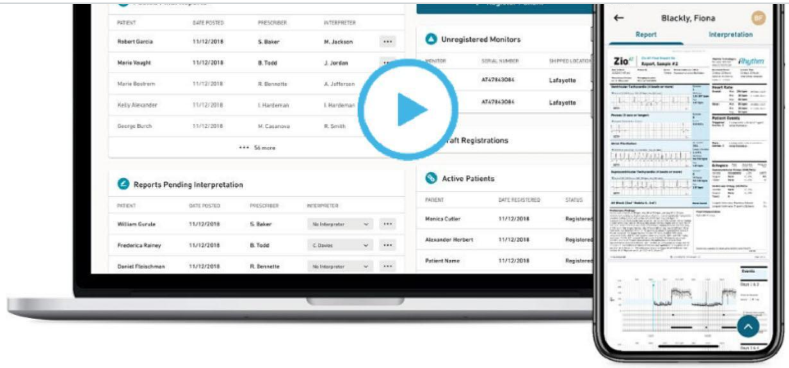
It's easy for your patients to apply a Zio monitor at home.



Patient care at your fingertips with ZioSuite.

ZioSuite is an intuitive and comprehensive web portal and mobile app for healthcare professionals that enables remote care, and streamlines clinical workflows. With ZioSuite, you can:

- Register patients remotely
- Order monitors to be sent to patients for Home Enrollment
- View and interpret patient reports from anywhere



Watch The Overview.

HOW HEALTH SYSTEMS ARE UTILIZING TELEHEALTH

Read how Spectrum Health is utilizing telehealth to create a new path forward for cardiovascular care of AFib patients in *Cardiology*.

READ NOW

See how a New York City medical center is thinking outside the box amid the chaos of COVID-19. Full webinar is now available for viewing.

WATCH NOW

Home Enrollment FAQs

WHAT IS HOME ENROLLMENT AND HOW DOES IT WORK?

What is Home Enrollment? +

Why consider Home Enrollment? +

How do I activate Home Enrollment for my clinic? +

Does Home Enrollment require an office visit for application or return?

Can my clinic bill for the hook-up of the monitor and what are the appropriate CPT codes?

Is there a delay to receiving the patient report?

PATIENT SUPPORT: HOW ARE MY PATIENTS EQUIPPED WITH THE RIGHT INFORMATION?

How are patients registered?

Who ships the monitor to the patients?

How soon will patients receive their monitor?

Will patients receive proper application instructions?

How will my patients receive customer support?

Will patients wear the monitor?

Contact Us

What best describes your role?

Request type*

Email*

I acknowledge and agree that iRhythm Technologies, Inc., iRhythm Technologies, Ltd. or an authorized representative (collectively, "iRhythm") may store and process my personal information in accordance with the terms of iRhythm's Privacy Policy. By submitting this form, you consent to iRhythm contacting you for purposes of marketing its products, services and events. You may unsubscribe at any time. For more information about iRhythm's processing of your personal information, you may review our Privacy Policy.*

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Exhibit 13

04-Dec-2024

iRhythm Technologies, Inc. (IRTC)

Citi Global Healthcare Conference

CORPORATE PARTICIPANTS

Daniel G. Wilson
Chief Financial Officer, iRhythm Technologies, Inc.

OTHER PARTICIPANTS

Joanne K. Wuensch
Analyst, Citigroup Global Markets, Inc.

MANAGEMENT DISCUSSION SECTION

[Abrupt Start]

Joanne K. Wuensch
Analyst, Citigroup Global Markets, Inc.

...Of iRhythm. I'm thrilled to have Dan Wilson here. Can I call you a new CFO still or...

Daniel G. Wilson
Chief Financial Officer, iRhythm Technologies, Inc.

Yeah. That's okay.

Joanne K. Wuensch
Analyst, Citigroup Global Markets, Inc.

That's okay.

Daniel G. Wilson
Chief Financial Officer, iRhythm Technologies, Inc.

Yeah, yeah.

Joanne K. Wuensch
Analyst, Citigroup Global Markets, Inc.

I'll call you an old CFO, how's that?

Daniel G. Wilson
Chief Financial Officer, iRhythm Technologies, Inc.

That's refreshment.

Joanne K. Wuensch
Analyst, Citigroup Global Markets, Inc.

So, anyway, someone newly minted CFO of iRhythm Technologies, Dan, thank you for joining us today.

Daniel G. Wilson
Chief Financial Officer, iRhythm Technologies, Inc.

Thank you for having us.

QUESTION AND ANSWER SECTION

Joanne K. Wuensch Q
Analyst, Citigroup Global Markets, Inc.

Excellent. So, a lot has happened for iRhythm over the last 12 months. And even if you think about it, for the patch technology market. So, if we could just sort of kick off broadly and just give us maybe a State of the Union of Patch Technology and how you're thinking about adoption?

Daniel G. Wilson A
Chief Financial Officer, iRhythm Technologies, Inc.

Yeah. So, from a market standpoint, we quantify our market being ambulatory cardiac monitoring in the US at 6.5 million tests. There's a lot of kind of mixed shift happening underneath that 6.5 million tests. But we have continued to see the overall market growing, call it mid-single digits. We do think there's an opportunity to really expand the market as we're making inroads into primary care, which I'm sure we will talk about it as well as asymptomatic screening. But a lot of our growth and the market growth has been driven by this mix shift from legacy short-term [ph] advent (00:03:40) monitoring technologies to patch-based technologies like Zio. And that has been true for the last several years and will continue to be true for the foreseeable future. Despite all our progress, there's still over a third of the market is using these legacy technologies in terms of short-term Holter and event monitoring. So, still a lot of opportunity for us to continue to shift those that modality to patch-based technology which we know is better both clinically and economically, and then a lot of opportunities to expand the market from primary care standpoint moving upstream and we're seeing really good progress there. And then ultimately to asymptomatic screening, which we're seeing early signs of as well.

Joanne K. Wuensch Q
Analyst, Citigroup Global Markets, Inc.

And how do you think today about the competitive landscape? I mean, if a third of the market is still – this is a two part question. The third of the market is still traditional Holter monitors, two-thirds is using some form of a patch technology, both what is it – what do you think about the competitive side of that two-thirds and what moves the one-third over?

Daniel G. Wilson A
Chief Financial Officer, iRhythm Technologies, Inc.

Yeah, maybe starting with the second part of that question first. Ultimately, I think it's an education. A matter of education, just getting out to, primary care physicians and other clinicians that are still leveraging those older

modalities and showing them the clinical and economic evidence. I mean, it is very clear that Zio and other patch-based technologies are better than legacy modalities. So, it's a matter of education, I think, how we've gone about it in terms of starting in cardiology and electrophysiology as the clinical champion, what we're seeing now is those clinicians helping educate primary care physicians upstream. It's ultimately better for them as well in terms of getting patients on Zio earlier in their care journey and ultimately the patients coming through to cardiology and electrophysiology have been kind of pre-qualified. Those are truly the patients that should be seen by cardiologists and electrophysiologist.

So, that's been encouraging that they've been a champion of this movement and expect that to continue. Within the competitive landscape of patch-based technologies, I'd say really we feel incredibly good about our competitive positioning. We've actually grown our share in long-term continuous monitoring and in that segment, long-term continuous monitoring by a point or two in the last couple of years and starting at 70%. So, pretty high base that we're growing from there. And really that's driven by Zio Monitor, our new form factor that is getting really good remarks in the field and certainly a better patient experience.

That form factor is 72% smaller than Zio XT, 55% lighter, better adhesive in terms of breathability and waterproofing. And our tagline when we launched Zio Monitor was the best just got better because Zio XT was already best-in-class from a form factor standpoint for Zio Monitor is a step change to that. So, that's been a great driver in terms of our competitive positioning and ultimately winning share in the market. And then, I would say just a steady drumbeat of clinical and economic data as well. We had CAMELOT data last year that was nearly 300,000 Medicare patients retrospective of showing Zio XT being best-in-class in terms of diagnostic yield, retest rate. And that has been a great kind of tool for our commercial team to drive account wins.

Joanne K. Wuensch Q
Analyst, Citigroup Global Markets, Inc.

So, I think this is a great place to start talking about the primary care physician. And if I remember correctly, earlier this year, there was a statistic that maybe 20% of your patches were already going into the PCP, first, correct me if that's the right number, but also walk through the mechanics of how you're approaching that segment?

Daniel G. Wilson A
Chief Financial Officer, iRhythm Technologies, Inc.

Yeah, yeah. Good question. So, yes, 20% – a little bit over 20% was the metric we gave, I think earlier this year, which was volume for 2023. That is, we haven't updated that metric, but we will at some point here and it does continue to grow as overall percent of our business and we expect that to fully continue. How we're approaching primary care? I think it's really kind of two approaches.

One, our business has always had this land and expand model where we open up an account again with our clinical champion, cardiology or electrophysiology, and then follow that into other departments in that account, whether it's emergency room, neurology, nephrology and primary care. That is kind of really been happening for several years and our best performing reps were kind of doing that organically, opening an account and then looking for those expansion opportunities. More recently in the last call it two, three years, we've structured our commercial team to really standardize that approach. We have our territory managers, certainly, but then another group called Key Account Managers that are really responsible for driving that expansion into those accounts.

So, that's been one way we're going after it, the other effort is with our Strategic Accounts Group, that's really focused on these innovative PCP groups that we've been talking about more and more, Signify, One Medical, et cetera. That's a small, dedicated team going after those accounts, it's a very attractive model in terms of kind of a

top down selling model, a one to many selling model. And a lot of those institutions like to kind of standardize care across their network. So, once they buy into Zio, they're generally adopting that across their network.

Joanne K. Wuensch
Analyst, Citigroup Global Markets, Inc.

Q

So, can we dig into this a little bit, because I think some of the accounts that you mentioned, the Signify and the One Medical, I remember correctly, have almost trial periods to see how the Zio patch might integrate into their practices. So, how do you approach getting either groups or an accounts just to...

Daniel G. Wilson
Chief Financial Officer, iRhythm Technologies, Inc.

A

Yeah.

Joanne K. Wuensch
Analyst, Citigroup Global Markets, Inc.

Q

...sort of say, okay, let me fold this in?

Daniel G. Wilson
Chief Financial Officer, iRhythm Technologies, Inc.

A

Yeah, yeah, certainly. So, it probably good to distinguish between symptomatic monitoring and asymptomatic monitoring. Symptomatic patients are generally getting served in one way or another. So, if they're buying into Zio, they're generally adopting Zio for all of their symptomatic patients. So, I might check.

Joanne K. Wuensch
Analyst, Citigroup Global Markets, Inc.

Q

Check, check.

Daniel G. Wilson
Chief Financial Officer, iRhythm Technologies, Inc.

A

Good. Okay. Yeah. In generally, they're adopting Zio for all of their symptomatic patients and that can be a pretty clean cut over. On the asymptomatic side, generally, they will start with a pilot that are trying to understand which patients they should be targeting with proactive monitoring. What are those patients that are coming back with arrhythmias and what to learn from there and then ultimately expand from there. Encouragingly, both Signify and PCC that we've talked about, adopting these asymptomatic monitoring programs, they've both and there are others like them have started with a pilot, have seen the value proposition play through, the ROI is meaningful to them and they've moved on to full commercial program. So, I think that's really encouraging. There's early signs here that that is going to be a meaningful opportunity for us. We did believe it would show up at some point. It was more a matter of when, not if. But we're starting to see some really encouraging signs there.

Joanne K. Wuensch
Analyst, Citigroup Global Markets, Inc.

Q

And is that kind of pilot program expected to be standard across the US or are there more that we'll hear about?

Daniel G. Wilson
Chief Financial Officer, iRhythm Technologies, Inc.

A

Yeah. Again, Signify and PCC are just two that we've talked about publicly. There are others like them, both active programs as well as kind of in the pipeline. And we'll certainly try to share more around those as we're ramping those. It does kind of cross over into our core business as well. There are institutions that have adopted Zio for their symptomatic patients have gotten experience with Zio. The clinicians love it, patients love it and then have expanded into asymptomatic monitoring as well. So, it isn't fully indistinguishable from our core business, which is why we don't break it out separately. But certainly, we'll give the qualitative color. And again, we're seeing really encouraging signs here.

Joanne K. Wuensch
Analyst, Citigroup Global Markets, Inc.
Q

Excellent. I am glad I didn't start with this, but I do you need to talk about some of the regulatory pathways. And if you could just sort of give us a State of the Union on what's happening with the FDA warning letter and congratulation on getting the two 510(k) approvals, specifically on that second one, what does that really mean?

Daniel G. Wilson
Chief Financial Officer, iRhythm Technologies, Inc.
A

Yeah. So, yeah, very encouraging progress there. We received the second of the two 510(k)s while we were live on our earnings call...

Joanne K. Wuensch
Analyst, Citigroup Global Markets, Inc.
Q

Was very dramatic. Thank you.

Daniel G. Wilson
Chief Financial Officer, iRhythm Technologies, Inc.
A

...very dramatic, but obviously a very encouraging that we received that. So, believe we're making very good progress to clearing the warning letter. The two 510(k)s were a very important milestone. In doing that, there was other remediation activities that are ongoing. And ultimately, the FDA will come back at some point for a closing inspection and confirm that we've done everything they were looking for us to do in terms of remediation efforts, specific to the warning letter, and then ultimately close that out at some point.

There are now also the 483 observations that we received in July. We put a response plan to the FDA in August, and we've been executing against that plan now for the last several months. We talked about hiring a new Head of Quality, and that individual has joined and has made a very big impact in a short amount of time. And we've talked about bringing in other consulting firms as well to support our efforts here. So, I believe we're doing everything that we should be doing and we're going to continue to make progress. And ultimately, we'll hear from the FDA at some point if they're satisfied with our progress or not. But we're focused on what we control and we're very confident in the plans that we have to address there.

Joanne K. Wuensch
Analyst, Citigroup Global Markets, Inc.
Q

Do you need to resolve the 483 observations to get the FDA warning letter lifted?

Daniel G. Wilson
Chief Financial Officer, iRhythm Technologies, Inc.
A

It's a good question. Ultimately, that is the FDA discretion. So, hard to speculate there. Those observations are distinct and different from what they called out in the warning letter. So, I think there is a scenario where we've addressed everything from a warning letter standpoint while still working through the 483 observations. And then, ultimately, it's the FDA's call to leave the warning letter outstanding while we're addressing the other 483 observations, or did they go ahead and clear up.

Joanne K. Wuensch Q
Analyst, Citigroup Global Markets, Inc.

Do you have a line of sight of all clear?

Daniel G. Wilson A
Chief Financial Officer, iRhythm Technologies, Inc.

I think, the timeline we've put out there both commitments to the FDA as well as activities that we're doing that it goes above and beyond what the FDA is asking us to do is through the end of next year.

Joanne K. Wuensch Q
Analyst, Citigroup Global Markets, Inc.

Correct.

Daniel G. Wilson A
Chief Financial Officer, iRhythm Technologies, Inc.

So, assuming we learn nothing between now and then or get confirmation from the FDA that they're satisfied with the approach that we're taking, I would say end of next year is when we would really feel good about having the remediation activities completed.

Joanne K. Wuensch Q
Analyst, Citigroup Global Markets, Inc.

And how do I [indiscernible] (00:15:46) this, what is the impact of the end of next year all clear remediation? Is it financial, is it product, is it approval?

Daniel G. Wilson A
Chief Financial Officer, iRhythm Technologies, Inc.

Yeah.

Joanne K. Wuensch Q
Analyst, Citigroup Global Markets, Inc.

Outside of popping champagne saying...

Daniel G. Wilson A
Chief Financial Officer, iRhythm Technologies, Inc.

Yeah.

Joanne K. Wuensch Q
Analyst, Citigroup Global Markets, Inc.

...okay, we've done this bridge. What happens?

Daniel G. Wilson A
Chief Financial Officer, iRhythm Technologies, Inc.

Yeah, it's certainly something we'll celebrate. And I think, if we were to fast forward to that time, I think we feel really good about the foundation that we built from a quality function standpoint, a quality management systems standpoint to be really that foundation and infrastructure needed to execute on all of our growth plans over the next decade. So, is it having a material impact on our business today? I wouldn't say it is, though it is our number one corporate priority, right. We've been very clear about that. And we've put other things to the side for the time being while we're focused on remediating the FDA's in concerns here. So, once we get that fully resolved and have that foundation built, I think we can reprioritize other innovation efforts that have kind of taken a little bit of a backburner at the time, for the time being.

Joanne K. Wuensch Q
Analyst, Citigroup Global Markets, Inc.

Okay. This sort of leads me into on the third quarter call, you delayed the next generation Zio MCT. Can you walk through A, what made you decide to do that? And B, how did you come about to quantifying it as a $10 million impact?

Daniel G. Wilson A
Chief Financial Officer, iRhythm Technologies, Inc.

Yeah. Yeah. So, importantly, that was voluntary and this was something we chose to do. It was not asked for by the FDA. But as we were reflecting on kind of what we've learned, as we've been going through this process, reflecting on the observations we received in July, engaging with our new quality leader, the new consulting firm that we've engaged, it was really through that dialogue we decided we need to take some time, make that submission for Zio MCT more robust. And it's really around some testing that just needs to be done really now that the qualified technician and the cardiac technician is considered part of the device, both from a quality management standpoint as well as a device clearance standpoint.

So, there's just testing work that needs to be done there. And unfortunately, the stuff that you just can't speed up just takes time to complete that testing. So, we're committed to doing that. That is the work that will take place over the next six months. We pointed to a Q3 submission timeline for Zio MCT and continue to feel good about that. In terms of the $10 million impact. It's interesting. AT is a good product and it is performing well. It is contributing to growth. We are very hard on that product. We know Zio MCT is ultimately the better product and does close some competitive gaps that exist with AT. But at the same time, AT does have competitive advantages of its own, certainly relative to competitors, which is why it continues to grow and take share in the market.

But again, we know Zio MCT is the better product. Our teams are incredibly excited about ultimately getting that to market and what we can do with that product. So, that is really what is behind that $10 million impact.

Joanne K. Wuensch Q
Analyst, Citigroup Global Markets, Inc.

So, what makes MCT a better product? And I'm really thinking about, this to me, you're very under-leveraged in the MCOT market. So, what makes this a better product and what makes it a product that allows you to take market share?

Daniel G. Wilson
Chief Financial Officer, iRhythm Technologies, Inc.

A

Yeah, the biggest thing to point to is 21 days of wear versus 14 days today with AT. We know that there's a view that MCT needs to be a 30-day, if not a 21-day kind of monitoring duration, whereas AT today only goes out to 14 days. We do have small amount of our patients that were back to back ATs, extend out to 28 days. But it's not a seamless process. So, with Zio MCT, getting out to 21 days is a meaningful change. And it's also on the new form factor. And we've seen what that means for Zio Monitor that I was referencing earlier. That is a very, very attractive form factor, certainly relative to existing form factor, but also other competitive devices out there.

So, that's a big driver. There will be algorithm improvements within the device as well in terms of its detection capabilities that trigger limit that we've talked about as it related to the warning letter, the number of patients that reach that trigger limit will be drastically reduced because of the better detection algorithm within Zio MCT as well. So, a number of benefits with Zio MCT, the really that 21 days of wear is to big one to point to.

Joanne K. Wuensch
Analyst, Citigroup Global Markets, Inc.

Q

And how does it compared to the competitive dynamics right now?

Daniel G. Wilson
Chief Financial Officer, iRhythm Technologies, Inc.

A

Yeah. So, this is where the advantage for AT and then certainly MCT. So, a patient can put it on and literally has to do nothing through the entire wear period, 14 days and 21 days. In terms of charging the device, swapping out an adhesive, swapping out electrode, that's different than our competitors. To get out to 21 days or 30 days, it requires the patient to recharge the device, swap out the adhesive, et cetera. And we know any time you introduce what we call patient manipulations in that time period, your patient compliance is going to be – that introduces friction and patient compliance suffers from that. So, in the consequences, you're not monitoring a patient and potentially missing out on arrhythmia when it happens. So, the advantage of AT and MCT is patient can put it on, they don't have to touch it and you get a full continuous 14 days and then 21 days of monitoring and capturing every single heartbeat in that time period. That's one thing.

The other, this is kind of a synergy from XT and Monitor is that end of wear report and that really is the product for XT and Monitor from a physician's perspective, right. That's what they receive at the end of the wear period. If you do channel checks, physicians will tell you they have extreme confidence in that report. They know and love it, have confidence that they can review that, in a matter of minutes and know exactly what's happening with that patient and can then move on to determining what's next for that patient. Physicians are receiving that same end of wear report for AT and MCT. So, if they're an adopter or a user of next monitor, they're going to get that same report for AT. And that is a nice some driver for AT and MCT.

Joanne K. Wuensch
Analyst, Citigroup Global Markets, Inc.

Q

Okay. And I think one of the things you mentioned, and I'm going to start moving a bit into the financials here, is the benefits of having them both on the same platform. And if you could just sort of start to think about or start to help us think about, where does the gross and operating leverage come from that similarity?

Daniel G. Wilson
Chief Financial Officer, iRhythm Technologies, Inc.

A

Yeah. So, yeah, Zio MCT will be on the same form factor that Zio Monitor is on currently. XT and AT look – the legacy form factors for us look the same, but the internal componentry is different, so they're manufactured on separate lines. With MCT and Monitor, they will be the same exact product and manufactured on a single line. And we have been – we've launched phase one of manufacturing automation. We have subsequent phases that will go live next year, in the year after, and really as we scale from a volume standpoint, from here forward, we're going to start to see that leverage from a manufacturing standpoint which will ultimately benefit gross margin.

That's on the device side, also within gross margin for us as the clinical operation expense in terms of the human component, labor component to deliver the service, I think there are more opportunities there to continue to be more and more efficient with how we deliver that service and there's an opportunity for improvement there. And as the detection algorithms improve, as our AI continues to improve, that will ultimately benefit gross margin as well. So, we expect to exit this year close to 70%. We believe, from a full year standpoint. We'll see a step up next year relative to full year, 2024. And then, we've we have a long-term target out there, 72% to 73% in 2027 and we're driving towards that.

Joanne K. Wuensch
Analyst, Citigroup Global Markets, Inc.

Q

And remind us of your long-term targets for 2027 for operating margins or adjusted EBITDA?

Daniel G. Wilson
Chief Financial Officer, iRhythm Technologies, Inc.

A

Yeah. So, for adjusted EBITDA, we called out 15% in 2027. Importantly, that is a moment in time, that isn't the ultimate goal and there's plenty of opportunities to continue to drive above and beyond that and we're focused on that. The cadence we're on right now is really 400 basis points to 500 basis points of adjusted EBITDA improvement year-to-year. And we've executed on that in the last couple of years. That's the expectation for next year as well. And that ultimately is putting us on a pace to exceed that 15%. So, we're on the right trajectory there. Back to the FDA remediation efforts, there is – and we called out $15 million of run rate expenses, which will continue into 2025. That is purely incremental in addressing the remediation efforts that are ongoing. So, ultimately, those will go away and that would drop to the bottom line, which would be a nice lever for us.

Joanne K. Wuensch
Analyst, Citigroup Global Markets, Inc.

Q

And everything you said, all of these LRP programs, if memory serves me in 2022.

Daniel G. Wilson
Chief Financial Officer, iRhythm Technologies, Inc.

A

Correct.

Joanne K. Wuensch
Analyst, Citigroup Global Markets, Inc.

Q

And a lot has happened since 2022.

Daniel G. Wilson
Chief Financial Officer, iRhythm Technologies, Inc.

A

Yeah.

Joanne K. Wuensch
Analyst, Citigroup Global Markets, Inc. Q

So, did the things you've done slowed down your ultimate LRP goal or maybe even accelerate it because you've taken a lot of steps that had to be done?

Daniel G. Wilson
Chief Financial Officer, iRhythm Technologies, Inc. A

From a profitability standpoint, yeah, again, we feel really good about the trajectory we're on...

Joanne K. Wuensch
Analyst, Citigroup Global Markets, Inc. Q

Yeah.

Daniel G. Wilson
Chief Financial Officer, iRhythm Technologies, Inc. A

...and achieving that 15% in the gross margin line. On the top line, Zio MCT is now two years delayed from when we initially set that target in 2022. We've been able to overcome that to this point with the success we're seeing in primary care expansion, asymptomatic screening and so some puts and takes there. Ultimately, we do need to get Zio MCT on the market to achieve that $1 billion target. So, we haven't backed away from that. It may be a bit delayed beyond 2027. If it's not 2027, it will be 2028 in terms of when we eclipse that $1 billion target.

Joanne K. Wuensch
Analyst, Citigroup Global Markets, Inc. Q

Got it. That's really helpful. What happens with other areas and other geographies? I sat at that analyst meeting in 2022 and it seemed five years from now this might be happening. And now I'm sitting here on the cusp for 2025 and I'm like, where are we? Or where are you in O-US?

Daniel G. Wilson
Chief Financial Officer, iRhythm Technologies, Inc. A

Yeah. So, yeah, I would say maybe back to the question earlier in terms of the puts and takes. International, I wouldn't say has gone faster than we were expecting when we set that target in 2022, but still feel good about the trajectory that we're on. We set up launched into four new Western European countries over the last few months and then we've been talking about Japan. We received PMDA approval there earlier this year. We're now in the reimbursement process. Japan alone is 1.5 million tests per year, all being done with short-term Holter. So, there's a real opportunity there in Japan for us to kind of change the standard of care like we've done in the US and shift to Zio and patch-based technologies.

Similarly, in the four European countries, collectively that represents another, call it, 1.5 million tests. And similarly, generally being done today short-term Holter. There are some smaller players from a patch-based technology standpoint and importantly, those four countries were chosen because of really for reimbursement purposes there. There is good reimbursement in place and each of those four countries and feel good about being able to kind of ramp our business within those countries. We're really just getting started. But do feel like international will be a growth driver for us in 2025 and then, 2026 and beyond.

Joanne K. Wuensch
Analyst, Citigroup Global Markets, Inc. Q

Did you put an RMP goal on the percentage of total revenue expected to come from O-US?

Daniel G. Wilson A
Chief Financial Officer, iRhythm Technologies, Inc.

We did, we called out 8% of that $1 billion target.

Joanne K. Wuensch Q
Analyst, Citigroup Global Markets, Inc.

And where are you tracking towards that now?

Daniel G. Wilson A
Chief Financial Officer, iRhythm Technologies, Inc.

So, today, before we launched in the four European countries, we're really just in UK and that's, low-single digit call it less than 2% of revenue.

Joanne K. Wuensch Q
Analyst, Citigroup Global Markets, Inc.

Yeah.

Daniel G. Wilson A
Chief Financial Officer, iRhythm Technologies, Inc.

UK remains an opportunity for us and now we're stacking four additional European countries and then ultimately Japan as we go into next year. So, continue to feel good about that growing certainly from that less than 2% to more in line with that 8% target.

Joanne K. Wuensch Q
Analyst, Citigroup Global Markets, Inc.

Okay. And what do you have to do to start selling these products? Is it a direct sales force, is it a distributor, is it a partnership?

Daniel G. Wilson A
Chief Financial Officer, iRhythm Technologies, Inc.

Yeah, it'll be a mix. For Spain and Japan, we'll be leveraging a distributor. For the other countries, we'll be going direct. Our businesses is a little bit different from kind of just a traditional med device company where you're selling a device and can hand that over to a distributor really to drive selling. We're a device enabled service. So, there is a bit of infrastructure and clinical operations buildout that needs to be done as well that we're doing for the four countries that I mentioned. We have that in the UK today. And then we'll have our clinical operations team supporting the Japan launch as well. So, a little bit more than just handing a device over to a distributor, but feel good about the infrastructure we're building and continuing to drive international expansion.

Joanne K. Wuensch Q
Analyst, Citigroup Global Markets, Inc.

So, but a part of the device is specialty is that you do have a human that looks at the data and downloads it and it creates a report. Are you able to do that regionally or is it self-funneled back maybe to somebody here in the United States?

Daniel G. Wilson
Chief Financial Officer, iRhythm Technologies, Inc.

A

Yeah, each country will be different.

Joanne K. Wuensch
Analyst, Citigroup Global Markets, Inc.

Q

Okay.

Daniel G. Wilson
Chief Financial Officer, iRhythm Technologies, Inc.

A

And this comes back to kind of the data privacy rules that each country has and each country is a little bit different. So, where we can leverage existing clinical operations, infrastructure, either the UK or US or other geographies, we'll look to do that or build it out within a country. If we fast forward and on our roadmap beyond the four countries Germany or France, that's likely going to require, staff in country. But those are later in our roadmap.

Joanne K. Wuensch
Analyst, Citigroup Global Markets, Inc.

Q

Okay. Is there anything that would slow the uptake of these products in the region once reimbursement – it sounds like reimbursement is in place culturally or professionally or and I'm trying to figure out why you wouldn't have a similar success on the transition to patch technology that you've...

Daniel G. Wilson
Chief Financial Officer, iRhythm Technologies, Inc.

A

Yeah.

Joanne K. Wuensch
Analyst, Citigroup Global Markets, Inc.

Q

...had in the United States?

Daniel G. Wilson
Chief Financial Officer, iRhythm Technologies, Inc.

A

I think it's a fair question, and I would argue, we have more clinical and economic evidence than we ever have, right...

Joanne K. Wuensch
Analyst, Citigroup Global Markets, Inc.

Q

Right.

Daniel G. Wilson
Chief Financial Officer, iRhythm Technologies, Inc.

A

...versus where we started with in the US many years ago. So, from that standpoint and a brand recognition standpoint. So, Zio is, despite only being really in the US today, it does have some global brand recognition given all of the clinical trial work that we've done and clinical evidence that we've generated. So, from that standpoint, I think we're starting in a really strong position. At the same time, changing behavior, changing standard of care,

takes time. And nothing ever moves fast enough in healthcare from my standpoint. So, I think it's right to not going to ahead of ourselves here. Ultimately, I think the opportunity is the same as what we've seen in the US in terms of fully shifting the standard of care to Zio.

Joanne K. Wuensch
Analyst, Citigroup Global Markets, Inc.

Q

Okay. Outside of these regions, do you have targets and if so, how do you approach them?

Daniel G. Wilson
Chief Financial Officer, iRhythm Technologies, Inc.

A

We do. We have enough kind of to go after the moment, right, with the four Western European countries as well as Japan. We'd like to kind of get some experience there, make sure we're not spreading ourselves too thin. So, we'll be focused on those countries for the near-term. There are others on the roadmap I mentioned Germany and France, but those are a bit further out.

Joanne K. Wuensch
Analyst, Citigroup Global Markets, Inc.

Q

And you've also been looking at other applications of the technology. I know we spoke briefly in the primary care arena, but maybe using it for post-field ablation patients, either in identification or post-surgery structural heart, for example. And I'll even throw sleep apnea into that group. I mean, how do you think about just pushing out the potential applications of the Zio technology?

Daniel G. Wilson
Chief Financial Officer, iRhythm Technologies, Inc.

A

Yeah, it's something we're really excited about and focused on. So, if you think about Zio today, we're really just taking the ECG signal from the patient and then providing insights. The insights we're providing today are really around arrhythmias, diagnosing and characterizing the arrhythmias. There's more we can do with just the ECG signal. And we've had some initial data around sleep and in terms of classifying sleeping activity and then ultimately overlaying where when arrhythmias are showing up, right. Is it in a state of sleep or in a state of activity, which is important clinical insights for a clinician.

So, there is more and more insights we know we can deliver through ECG alone. Where it gets really exciting is when we start to bring other vital signs monitoring onto the platform. And this goes back to the licensing transaction we did with BioIntelliSense last quarter, where we will now start to build pulse ox, blood pressure, respiratory rate, other vital signs onto the platform. And as you're capturing more and more patient data, it really opens the aperture in terms of insights that you can deliver. And certainly from sleep standpoint, we believe we can deliver a home sleep test with those vital signs. And so, that will be kind of the next platform build and really excited about what that can mean for us.

Joanne K. Wuensch
Analyst, Citigroup Global Markets, Inc.

Q

And is that something you do on your own or is that something you've done in partnership with others?

Daniel G. Wilson
Chief Financial Officer, iRhythm Technologies, Inc.

A

So, we did license that technology from BioIntelliSense. Now is kind of in the build phase and some of that will be internal, some of that will be external. I think we're open to bringing the outside in terms of supporting those efforts. We have high confidence in our R&D capabilities, but we know we can't do everything that we want to do. So, I think there is an opportunity to leverage the outside to complement what we can do internally and really drive some pretty exciting innovation.

Joanne K. Wuensch
Analyst, Citigroup Global Markets, Inc.

Q

And what about in structural heart? And then pulsed field ablation, where do you see those Zio Patch fitting?

Daniel G. Wilson
Chief Financial Officer, iRhythm Technologies, Inc.

A

Yeah, I think both opportunities we do get questions a lot on PFA today. I mean that is a very exciting opportunity in the market. And I would say there is a, there's a buzz and excitement in electrophysiology that hasn't been there for some time.

Joanne K. Wuensch
Analyst, Citigroup Global Markets, Inc.

Q

Yeah.

Daniel G. Wilson
Chief Financial Officer, iRhythm Technologies, Inc.

A

And ultimately when the downstream therapies are improving like, like we're seeing with pulsed field ablation, it's logical to think about the upstream diagnostics improving with it. So, we're seeing that it is a nice tailwind for, for the business. Ultimately those patients need to be diagnosed and into the funnel for PFA procedures and then ultimately, subsequently monitor post procedure as well. So, as that market grows, we expect to see benefits and we are we are seeing benefits there as well.

Joanne K. Wuensch
Analyst, Citigroup Global Markets, Inc.

Q

Excellent. So, when you and I are talking this time next year, what do you think we're going to be talking about? Or maybe the better question is, what do you think, we're not going to be talking about?

Daniel G. Wilson
Chief Financial Officer, iRhythm Technologies, Inc.

A

Yeah. I won't surprise anyone with this answer. Well, I hope we are talking about, successfully remediating the quality management system that we're really transforming. And back to that comment earlier about building the foundation and infrastructure to support that next major phase of growth for us. I hope that's what we're talking about, that that foundation is built and all of the exciting growth opportunities are more and more real for us and have great plans to get after them.

Joanne K. Wuensch
Analyst, Citigroup Global Markets, Inc.

Wonderful. Dan, thank you so much for joining us today.

Daniel G. Wilson

Chief Financial Officer, iRhythm Technologies, Inc.

Thank you very much. Appreciate it.

Joanne K. Wuensch

Analyst, Citigroup Global Markets, Inc.

Okay.

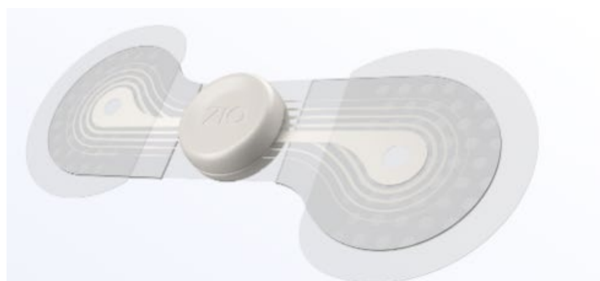
EXHIBIT 14

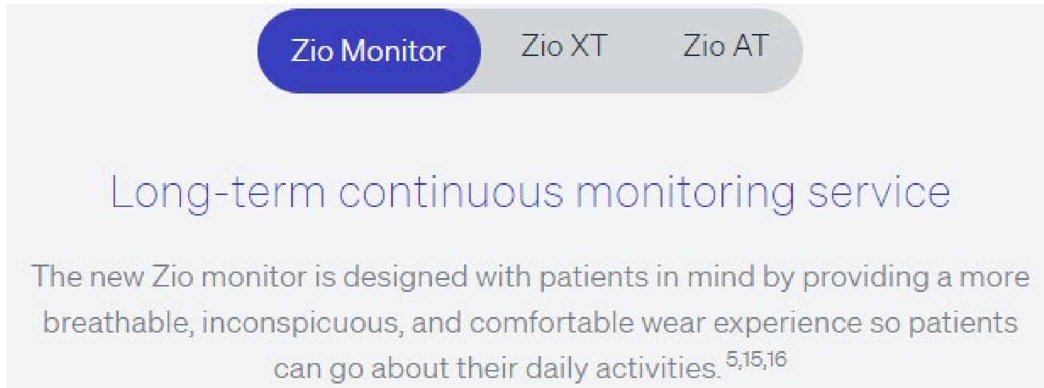
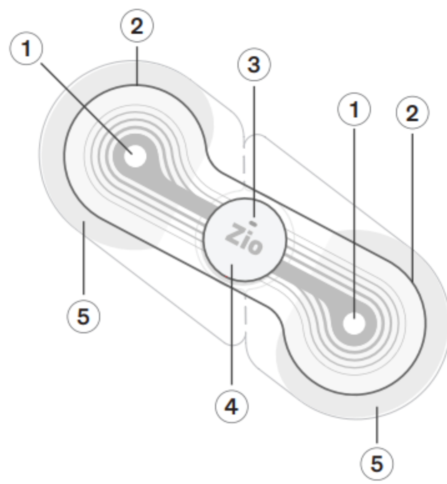
Claim Chart for U.S. Patent No.12,161,473 ("the '473 Patent")

The Accused Instrumentalities include, but are not necessarily limited to, the Next-Generation Zio Monitor by iRhythm (the "Zio Monitor"). The Accused Instrumentalities infringe at least the claims of the '473 Patent charted below either directly under 35 U.S.C. § 271(a), or indirectly under 35 U.S.C. §§ 271(b)–(c). The Accused Instrumentalities infringe such claims literally and/or under the doctrine of equivalents.

Claim 1	**Accused Instrumentalities**
1[pre] A wearable electrocardiography monitoring device, comprising:	***To the extent the preamble is deemed to be a limitation, the Accused Instrumentalities include a wearable electrocardiography monitoring device in accordance with this claim.*** The Zio Monitor satisfies 1[pre] because the Zio Monitor is a device that is worn on the patient's body. In an example, the Zio Monitor monitors patient ECG signals.  Zio Monitor (https://s201.q4cdn.com/653785554/files/doc_downloads/V4_-_iRhythm_ESG_Report_2023.pdf)

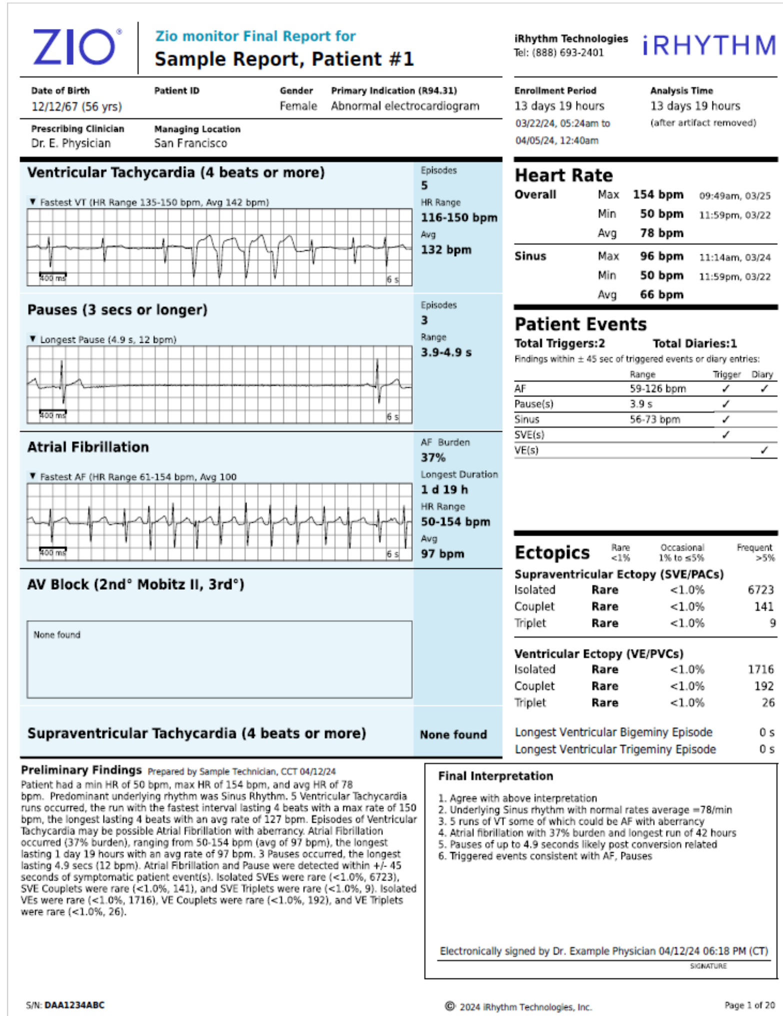
321652514.2

Claim 1	**Accused Instrumentalities**
	ZIO MONITOR SYSTEM The Zio Monitor System is the next generation of the Zio XT System, and is a prescription-only, remote ECG monitoring system that consists of the Zio Monitor patch that records the electric signal from the heart continuously for up to 14 days and the ZEUS System, which supports the capture and analysis of ECG data recorded by the Zio Monitor patch at the end of the wear period, including specific arrhythmia events detected by the ZEUS algorithm. (https://s201.q4cdn.com/653785554/files/doc_downloads/V4_-_iRhythm_ESG_Report_2023.pdf)  **Next-generation Zio® monitor** Long-Term Continuous Monitoring Service Introducing the Zio monitor—designed to be lighter, smaller, and thinner, while building on the high performance of Zio XT.[5-8] (https://www.irhythmtech.com/providers/zio-service/zio-monitors)

Claim 1	**Accused Instrumentalities**
	 Zio Monitor Zio XT Zio AT Long-term continuous monitoring service The new Zio monitor is designed with patients in mind by providing a more breathable, inconspicuous, and comfortable wear experience so patients can go about their daily activities.[5,15,16] (https://www.irhythmtech.com/providers/zio-service/zio-monitors) Example of Zio monitor  1 Electrode – acquires ECG data 2 Adhesive wings – adheres the Zio monitor to the upper-left chest 3 Light – momentarily flashes green when activated and orange in the event of an error. After activation, you will not see any lights. Refer to Troubleshooting - flashing lights on page 17. 4 Zio button – activates the Zio monitor. The patient presses this button when a symptom is felt. 5 Clear plastic backings – remove from back of Zio monitor and discard before applying to the chest. (https://go.irhythmtech.com/hubfs/LB10117.01%20-%20ZIO%20MONITOR%20INSTRUCTIONS%20FOR%20USE%2c%20PRINTED%20(2).pdf)

Claim 1	Accused Instrumentalities
	The Zio monitor is a single-use ECG monitor that provides a continuous, single-channel recording for up to 14 days. The Zio monitor records ECG data without patient interaction, with the goal of improving patient compliance via simplicity of operation. Patients have the option of pressing a convenient button and filling out a log to document symptomatic events, which will support symptom-rhythm correlation in the diagnostic report. (https://go.irhythmtech.com/hubfs/LB10117.01%20-%20ZIO%20MONITOR%20INSTRUCTIONS%20FOR%20USE%2c%20PRINTED%20(2).pdf) **Intended use** The Zio monitor is intended to capture symptomatic and asymptomatic cardiac events in a continuous electrocardiogram record for long-term monitoring. **Indications for use** The Zio monitor is a prescription-only, single-use ECG monitor that continuously records data for up to 14 days. It is indicated for use on patients who may be asymptomatic or who may suffer from transient symptoms such as palpitations, shortness of breath, dizziness, lightheadedness, pre-syncope, syncope, fatigue, or anxiety. (https://go.irhythmtech.com/hubfs/LB10117.01%20-%20ZIO%20MONITOR%20INSTRUCTIONS%20FOR%20USE%2c%20PRINTED%20(2).pdf)

<table>
<tr><th><u>Claim 1</u></th><th><u>Accused Instrumentalities</u></th></tr>
<tr><td></td><td>



ZIO® | Zio monitor Final Report for
Sample Report, Patient #1

iRhythm Technologies
Tel: (888) 693-2401
iRHYTHM

Date of Birth	Patient ID	Gender	Primary Indication (R94.31)
12/12/67 (56 yrs)		Female	Abnormal electrocardiogram

Prescribing Clinician: Dr. E. Physician
Managing Location: San Francisco

Enrollment Period: 13 days 19 hours, 03/22/24, 05:24am to 04/05/24, 12:40am
Analysis Time: 13 days 19 hours (after artifact removed)

Ventricular Tachycardia (4 beats or more)
▼ Fastest VT (HR Range 135-150 bpm, Avg 142 bpm)
Episodes 5; HR Range 116-150 bpm; Avg 132 bpm

Pauses (3 secs or longer)
▼ Longest Pause (4.9 s, 12 bpm)
Episodes 3; Range 3.9-4.9 s

Atrial Fibrillation
▼ Fastest AF (HR Range 61-154 bpm, Avg 100
AF Burden 37%; Longest Duration 1 d 19 h; HR Range 50-154 bpm; Avg 97 bpm

AV Block (2nd° Mobitz II, 3rd°)
None found

Supraventricular Tachycardia (4 beats or more) None found

Heart Rate

Overall	Max	154 bpm	09:49am, 03/25
	Min	50 bpm	11:59pm, 03/22
	Avg	78 bpm	
Sinus	Max	96 bpm	11:14am, 03/24
	Min	50 bpm	11:59pm, 03/22
	Avg	66 bpm	

Patient Events
Total Triggers:2 Total Diaries:1
Findings within ± 45 sec of triggered events or diary entries:

	Range	Trigger	Diary
AF	59-126 bpm	✓	✓
Pause(s)	3.9 s	✓	
Sinus	56-73 bpm	✓	
SVE(s)		✓	
VE(s)			✓

Ectopics Rare <1%, Occasional 1% to ≤5%, Frequent >5%

Supraventricular Ectopy (SVE/PACs)			
Isolated	Rare	<1.0%	6723
Couplet	Rare	<1.0%	141
Triplet	Rare	<1.0%	9
Ventricular Ectopy (VE/PVCs)			
Isolated	Rare	<1.0%	1716
Couplet	Rare	<1.0%	192
Triplet	Rare	<1.0%	26

Longest Ventricular Bigeminy Episode 0 s
Longest Ventricular Trigeminy Episode 0 s

Preliminary Findings Prepared by Sample Technician, CCT 04/12/24
Patient had a min HR of 50 bpm, max HR of 154 bpm, and avg HR of 78 bpm. Predominant underlying rhythm was Sinus Rhythm. 5 Ventricular Tachycardia runs occurred, the run with the fastest interval lasting 4 beats with a max rate of 150 bpm, the longest lasting 4 beats with an avg rate of 127 bpm. Episodes of Ventricular Tachycardia may be possible Atrial Fibrillation with aberrancy. Atrial Fibrillation occurred (37% burden), ranging from 50-154 bpm (avg of 97 bpm), the longest lasting 1 day 19 hours with an avg rate of 97 bpm. 3 Pauses occurred, the longest lasting 4.9 secs (12 bpm). Atrial Fibrillation and Pause were detected within +/- 45 seconds of symptomatic patient event(s). Isolated SVEs were rare (<1.0%, 6723), SVE Couplets were rare (<1.0%, 141), and SVE Triplets were rare (<1.0%, 9). Isolated VEs were rare (<1.0%, 1716), VE Couplets were rare (<1.0%, 192), and VE Triplets were rare (<1.0%, 26).

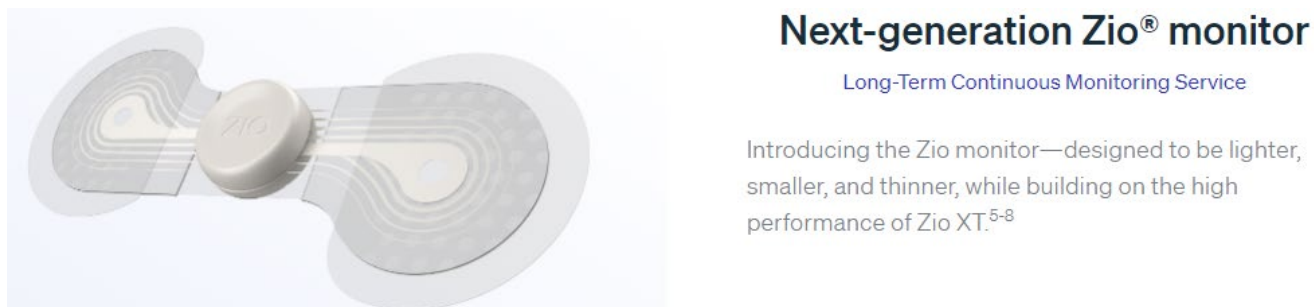
Final Interpretation
1. Agree with above interpretation
2. Underlying Sinus rhythm with normal rates average =78/min
3. 5 runs of VT some of which could be AF with aberrancy
4. Atrial fibrillation with 37% burden and longest run of 42 hours
5. Pauses of up to 4.9 seconds likely post conversion related
6. Triggered events consistent with AF, Pauses

Electronically signed by Dr. Example Physician 04/12/24 06:18 PM (CT)
SIGNATURE

S/N: DAA1234ABC © 2024 iRhythm Technologies, Inc. Page 1 of 20

(https://www.irhythmtech.com/providers/zio-service/reporting)
</td></tr>
</table>

Claim 1	**Accused Instrumentalities**
1[a] a flexible backing including a strip comprising:	***The Accused Instrumentalities include a flexible backing including a strip.*** The Zio Monitor satisfies 1[a] because the Zio Monitor includes a flexible backing including a strip. The new Zio monitor: The new Zio monitor is designed to be effortless to wear with increased adherence and better patient comfort. It's small enough for patients to forget they are wearing it through exercise, showering, and sleeping. The new design is more than 50% lighter than the current generation, and includes a new breathable and waterproof outer layer. It also has an improved 'stay-put' adhesive and a more flexible design for a secure attachment. These refinements will allow for a more comfortable wear and, therefore, more complete, accurate diagnostic data. (https://www.irhythmtech.com/company/news/irhythm-technologies-continues-to-fuel-innovation-in-cardiac-monitoring-and-unveils-two-fda-clearances-for-superior-patient-care) The Zio patches include the following features: • patented flexible, lightweight, wire-free design; • unobtrusive and inconspicuous profile; • proprietary adhesive backing designed to keep the Zio patch securely in place for the duration of the prescribed wear period; (https://s201.q4cdn.com/653785554/files/doc_downloads/V4_-_iRhythm_ESG_Report_2023.pdf) wearable medical device and a biosensor onto that small form factor. So, miniaturization was focused on very clever ways of handling some of the larger components, which for example involved moving some of the big resistors that are required on the device to the more flexible part of the patch instead of on the actual printed circuit board in the housing. And this is a patented feature that we've already (https://www.mddionline.com/cardiovascular/behind-the-design-how-irhythm-built-its-new-zio-monitor)

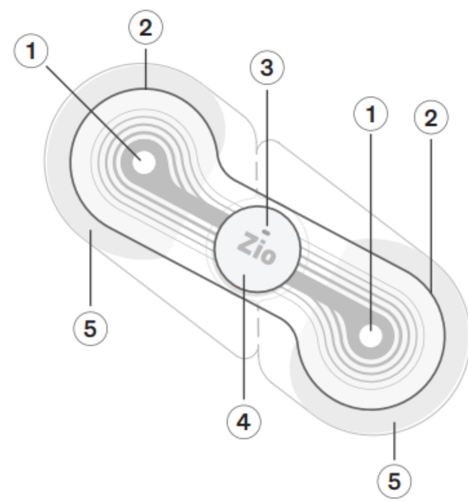
<u>**Claim 1**</u>	<u>**Accused Instrumentalities**</u>
	 Zio Monitor (https://s201.q4cdn.com/653785554/files/doc_downloads/V4_-_iRhythm_ESG_Report_2023.pdf)  (https://www.irhythmtech.com/providers/zio-service/zio-monitors)

<table>
<tr><th>Claim 1</th><th>Accused Instrumentalities</th></tr>
<tr><td>1[b] a first face and a second face, wherein a portion of the first face is covered in adhesive to adhere the strip to skin of a patient,</td><td>The Accused Instrumentalities include a first face and a second face, wherein a portion of the first face is covered in adhesive to adhere the strip to skin of a patient. The Zio Monitor satisfies 1[b] because the Zio Monitor includes an under side (i.e., a first face) and an upper side (i.e., a second face). A portion of the under side is covered in adhesive to adhere the strip to skin of a patient.

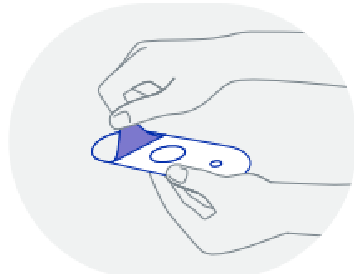
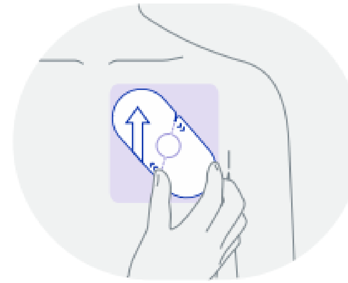

(Zio Monitor Teardown)

(Zio Monitor Teardown)</td></tr>
</table>

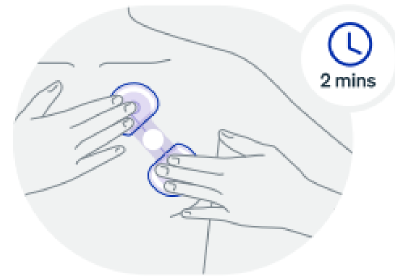
321652514.2

Claim 1	**Accused Instrumentalities**
	Example of Zio monitor  1 Electrode – acquires ECG data 2 Adhesive wings – adheres the Zio monitor to the upper-left chest 3 Light – momentarily flashes green when activated and orange in the event of an error. After activation, you will not see any lights. Refer to Troubleshooting - flashing lights on page 17. 4 Zio button – activates the Zio monitor. The patient presses this button when a symptom is felt. 5 Clear plastic backings – remove from back of Zio monitor and discard before applying to the chest. (https://go.irhythmtech.com/hubfs/LB10117.01%20-%20ZIO%20MONITOR%20INSTRUCTIONS%20FOR%20USE%2c%20PRINTED%20(2).pdf)

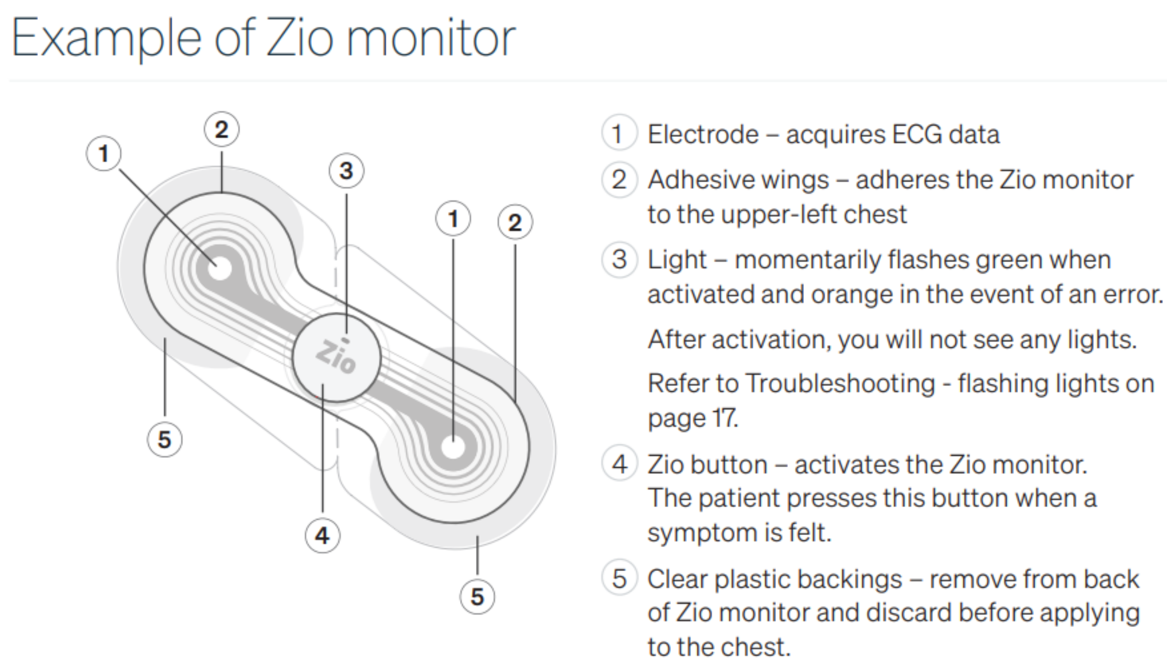
321652514.2

Claim 1	Accused Instrumentalities
	 **2. Peel clear backings:** a. Hold the middle of the Zio monitor. b. Pull off the clear plastic backings carefully and avoid touching the exposed adhesive. c. Keep the paper tabs intact on the other side of the monitor. Note: Wait to remove the paper tabs in Step 5.  **3. Apply the Zio monitor:** a. Ensure the white arrow on the paper tab is pointing upward. b. Place the Zio monitor diagonally on the prepared skin area, one finger width below the left collarbone from the center of the upper-left chest. (https://go.irhythmtech.com/hubfs/LB10117.01%20-%20ZIO%20MONITOR%20INSTRUCTIONS%20FOR%20USE%2c%20PRINTED%20(2).pdf)

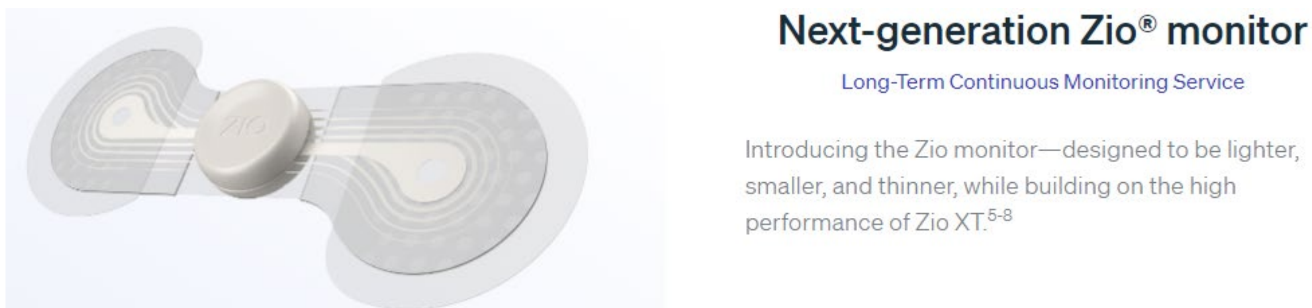
321652514.2

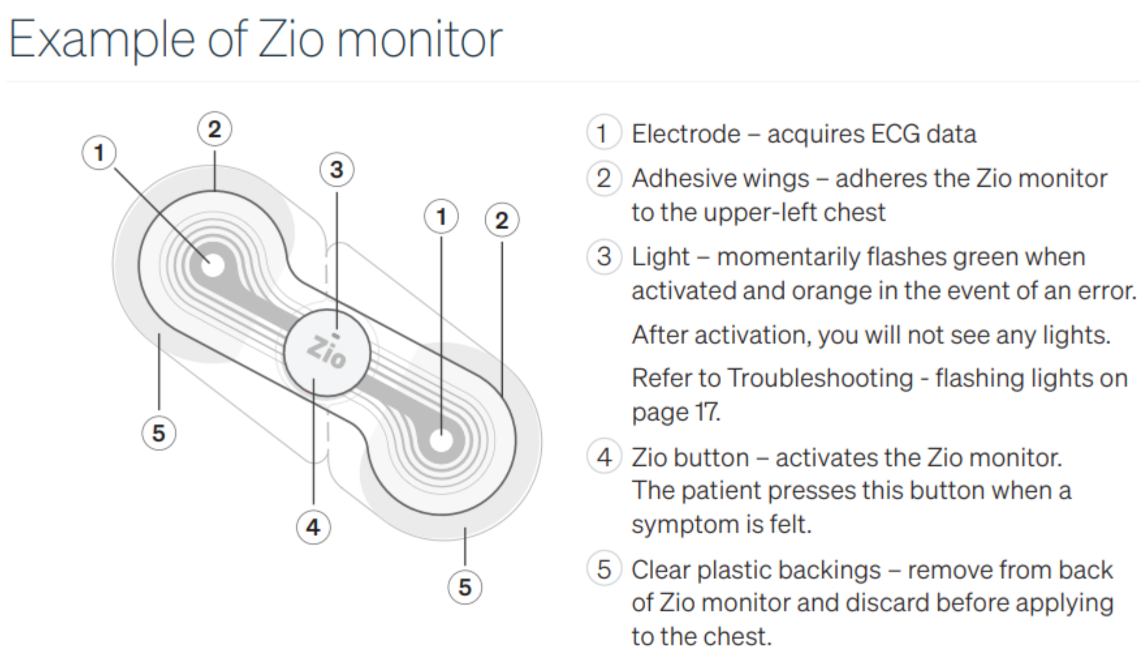
Claim 1	Accused Instrumentalities
	 **6. Massage wings again:** a. Massage the adhesive wings firmly onto the skin for another 2 minutes to prevent the Zio monitor from slipping or falling off the chest. (https://go.irhythmtech.com/hubfs/LB10117.01%20-%20ZIO%20MONITOR%20INSTRUCTIONS%20FOR%20USE%2c%20PRINTED%20(2).pdf) The new Zio monitor: The new Zio monitor is designed to be effortless to wear with increased adherence and better patient comfort. It's small enough for patients to forget they are wearing it through exercise, showering, and sleeping. The new design is more than 50% lighter than the current generation, and includes a new breathable and waterproof outer layer. It also has an improved 'stay-put' adhesive and a more flexible design for a secure attachment. These refinements will allow for a more comfortable wear and, therefore, more complete, accurate diagnostic data. (https://www.irhythmtech.com/company/news/irhythm-technologies-continues-to-fuel-innovation-in-cardiac-monitoring-and-unveils-two-fda-clearances-for-superior-patient-care)

Claim 1	Accused Instrumentalities
	The Zio patches include the following features: • patented flexible, lightweight, wire-free design; • unobtrusive and inconspicuous profile; • proprietary adhesive backing designed to keep the Zio patch securely in place for the duration of the prescribed wear period; (https://s201.q4cdn.com/653785554/files/doc_downloads/V4_-_iRhythm_ESG_Report_2023.pdf)

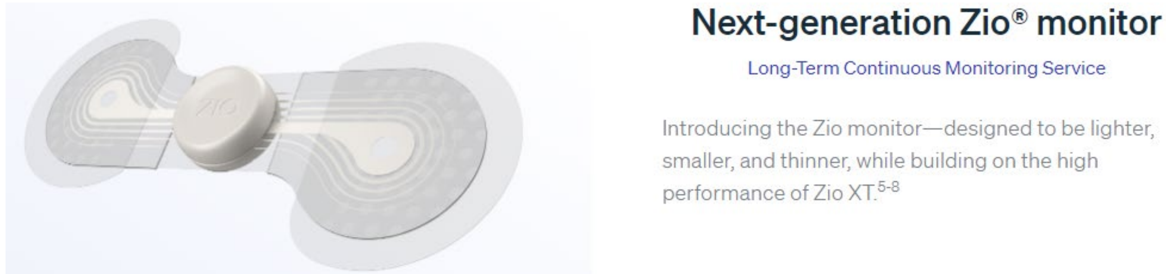
Claim 1	**Accused Instrumentalities**
1[c] a first end section, a second end section opposite the first end section, and a mid-section between the first end section and the second end section, wherein the mid-section is narrower than the first end section and the second end section;	***The Accused Instrumentalities include a first end section, a second end section opposite the first end section, and a mid-section between the first end section and the second end section.*** The Zio Monitor satisfies 1[c] because the Zio Monitor includes a first end section that is opposite a second end section. The Zio Monitor also includes a mid-section between the first end section and the second end section that is narrower than the first and second end sections as depicted below.  (https://go.irhythmtech.com/hubfs/LB10117.01%20-%20ZIO%20MONITOR%20INSTRUCTIONS%20FOR%20USE%2c%20PRINTED%20(2).pdf)

321652514.2

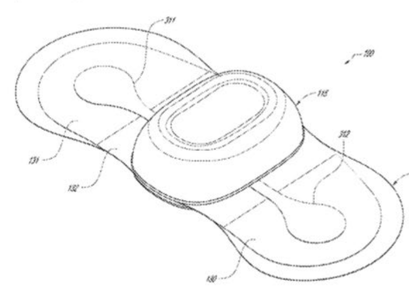
<u>**Claim 1**</u>	<u>**Accused Instrumentalities**</u>
	 (Zio Monitor Teardown)  (https://www.irhythmtech.com/providers/zio-service/zio-monitors)

<table>
<tr><th><u>Claim 1</u></th><th><u>Accused Instrumentalities</u></th></tr>
<tr><td>1[d] a flexible circuit mounted to the second face of the strip, the flexible circuit comprising a first circuit trace and a second circuit trace;</td><td>The Accused Instrumentalities include a flexible circuit mounted to the second face of the strip, the flexible circuit comprising a first circuit trace and a second circuit trace. The Zio Monitor satisfies 1[d] because the Zio Monitor includes a flexible circuit comprising two circuit traces (i.e., a first circuit trace and a second circuit trace). The flexible circuit is mounted to the upper side of the strip (i.e., second face).


(https://go.irhythmtech.com/hubfs/LB10117.01%20-%20ZIO%20MONITOR%20INSTRUCTIONS%20FOR%20USE%2c%20PRINTED%20(2).pdf)</td></tr>
</table>

<u>Claim 1</u>	**<u>Accused Instrumentalities</u>**
	 (https://www.irhythmtech.com/providers/zio-service/zio-monitors)  (Zio Monitor Teardown)

321652514.2

<u>**Claim 1**</u>	<u>**Accused Instrumentalities**</u>
	(12) **United States Patent** **Abercrombie, II et al.** (10) **Patent No.: US 11,399,760 B2** (45) **Date of Patent: *Aug. 2, 2022** (54) **WEARABLE DEVICE WITH CONDUCTIVE TRACES AND INSULATOR** (71) Applicant: **iRhythm Technologies, Inc.**, San Francisco, CA (US) (72) Inventors: **Jeffrey Joseph Abercrombie, II**, Oakland, CA (US); **Genaro Sebastian Sepulveda**, Oakland, CA (US); **Shena Hae Park**, San Francisco, CA (US); **Ryan James Wensley**, San Francisco, CA (US); **James Kihyun Lee**, San Francisco, CA (US); **Thomas Burnell Reeve, III**, San Francisco, CA (US) (73) Assignee: **IRhythm Technologies, Inc.**, San Francisco, CA (US) (*) Notice: Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 0 days. This patent is subject to a terminal disclaimer. (21) Appl. No.: **17/671,403** (22) Filed: **Feb. 14, 2022** (65) **Prior Publication Data** US 2022/0160279 A1 May 26, 2022 **Related U.S. Application Data** (63) Continuation of application No. 17/396,463, filed on Aug. 6, 2021, now Pat. No. 11,246,523. (Continued) (51) **Int. Cl.** ***A61B 5/00*** (2006.01) ***A61B 5/257*** (2021.01) (Continued) (52) **U.S. Cl.** CPC .... ***A61B 5/257*** (2021.01); ***A61B 5/282*** (2021.01); ***A61B 5/6833*** (2013.01); ***H05K 1/147*** (2013.01); (Continued) (58) **Field of Classification Search** CPC .... A61B 5/257; A61B 5/325; A61B 5/6833; A61B 5/6843; A61B 2090/0807; (Continued) (56) **References Cited** U.S. PATENT DOCUMENTS 1,497,079 A 6/1924 Gullborg 2,179,922 A 11/1939 Dana (Continued) FOREIGN PATENT DOCUMENTS AU 2011252998 8/2015 AU 2014209376 6/2017 (Continued) OTHER PUBLICATIONS US 8,750,980 B2, 06/2014, Katra et al. (withdrawn) (Continued) *Primary Examiner* — Eun Hwa Kim *Assistant Examiner* — Adam Z Minchella (74) *Attorney, Agent, or Firm* — Knobbe, Martens, Olson & Bear, LLP (57) **ABSTRACT** The present disclosure relates to a wearable device that includes a housing, battery terminal connector, conductive traces, and an insulator for recording signals. The device may include a housing enclosing a circuit board and a battery. The device may include two conductive traces electrically connected to terminals of the battery and an insulator separating the conductive traces. The battery terminal connector can present both the conductive traces to the outer surface for coupling to a circuit board. The device can assess the physiological signals to infer a likelihood of arrhythmia of a user. **30 Claims, 42 Drawing Sheets**  (https://patentimages.storage.googleapis.com/12/7b/34/ee9a6b3db2a824/US11399760.pdf)

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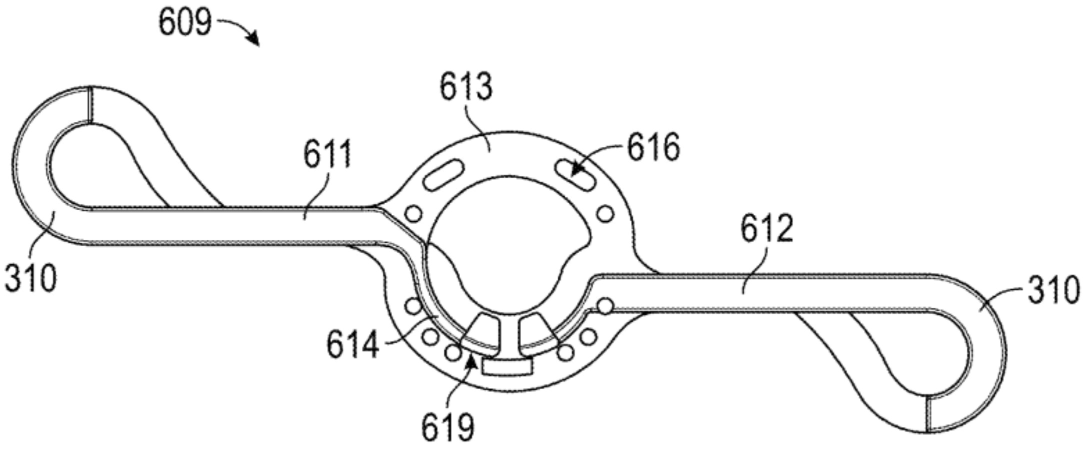
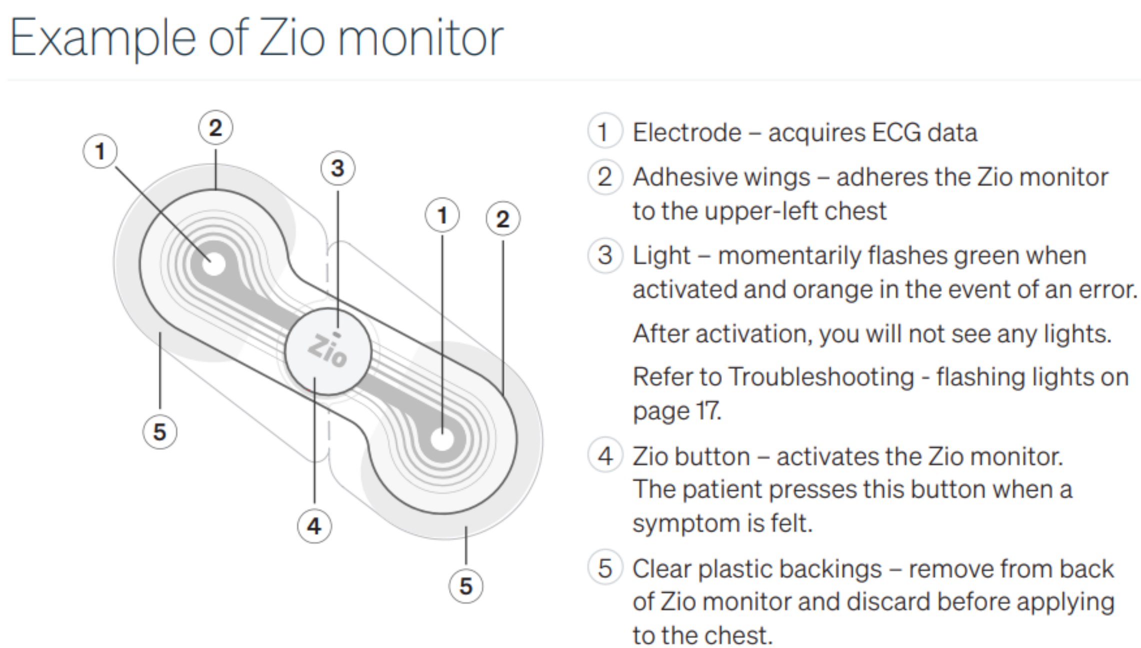
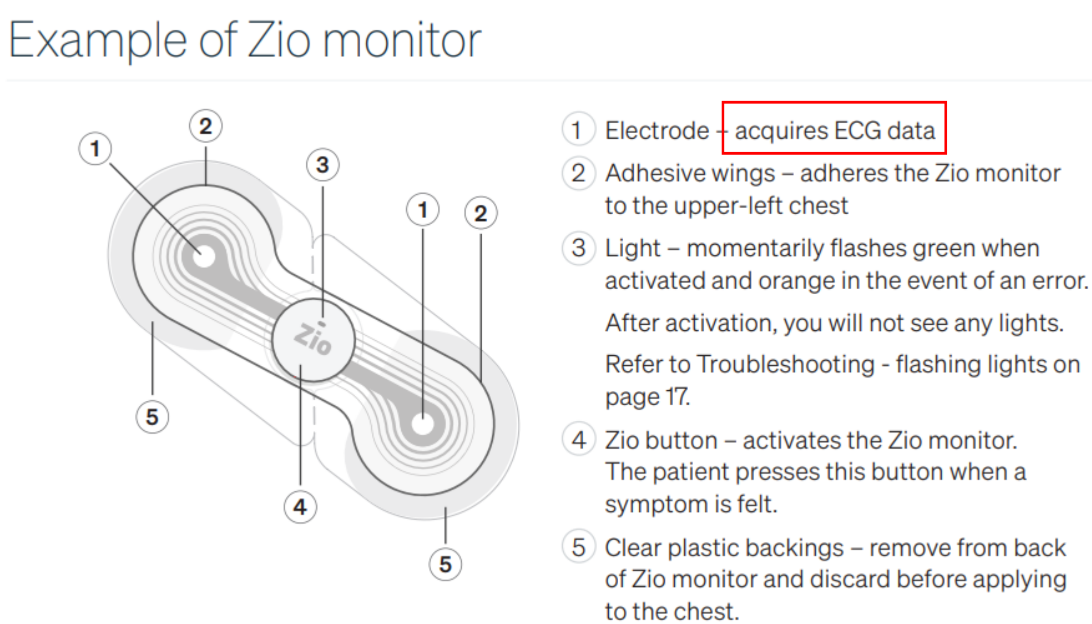
Claim 1	**Accused Instrumentalities**
	FIGS. **10A-10C** schematically illustrate alternative examples of trace layer **609**. The trace layer **609** may comprise an electrical trace **611**, **612** for each electrode **350** (such as shown in FIG. **3**B) of the physiological monitoring device **100**. The electrical traces **611**, **612** may be disposed on (e.g., printed onto) a non-conductive insulating layer **613**. In some embodiments, the insulating layer **613** may comprise a polyester, such as polyethylene terephthalate (PET) and/or another non-conductive polymer. One or more of the electrical traces **611**, **612** may be disposed on the same insulating layer **613**. The insulating layer **613** may be configured to maintain a separation between the electrical traces **611**, **612** that are coupled to distinct electrodes **350**. The electrical traces **611**, **612** may extend from the electrodes **350** into the housing **115** to make electrical contact with the PCBA **120**. In some embodiments, such as embodiments in which the physiological monitoring device **100** comprises two opposite wings **130**, **131** arranged generally collinear with one another, the electrical traces **611**, **612** may extend generally collinearly along a direction defining a longitudinal axis of the device. A transverse axis may be defined substantially perpendicular to the longitudinal axis. The longitudinal axis and/or the transverse axis may substantially bisect the housing **115** of the physiological monitoring device **100**. (https://patentimages.storage.googleapis.com/12/7b/34/ee9a6b3db2a824/US11399760.pdf)

Claim 1	Accused Instrumentalities
	 FIG. 10C (https://patentimages.storage.googleapis.com/12/7b/34/ee9a6b3db2a824/US11399760.pdf)

Claim 1	Accused Instrumentalities
	This web page is provided to satisfy the virtual patent marking provisions of various jurisdictions including the virtual patent marking provisions of the America Invents Act and provide notice under 35 U.S.C. §287(a), that the iRhythm Technologies' Zio patch products and related services, including but not limited to the Zio patch, Zio XT, Zio AT, and Zio MCT trademarked products, are covered by or for use under one or more of the patents listed below. Zio patch products and related services are covered by or for use under one or more international patents or international patent applications. Zio patch products and related services not listed here may be protected by one or more patents in the United States and other international jurisdictions and may be covered by patents in the United States and other international jurisdictions that are not listed. iRhythm Technologies' Zio patch products and related services may be sold individually or as part of a combination product or system. US Patent Numbers*: 8,538,503; 8,560,046; 9,173,670; 9,241,649; 9,451,975; 9,597,004; 9,955,887; 10,098,559; 10,271,754; 10,299,691; D852965; D854167; 10,405,799; 10,517,500; 11,141,091; 10,555,683; 11,627,902; 11,051,738; 10,667,712; 10,813,565; 11,605,458; 11,289,197; 11,350,864; 11,350,865; 11,589,792; 11,337,632; 11,504,041; 11,246,523; 11,399,760; 11,246,524; 11,382,555; 11,083,371; 11,253,185; 11,253,186; 11,375,941 and 11,497,432. Additional patents are pending in the United States. (https://www.irhythmtech.com/content/patents-trademarks)

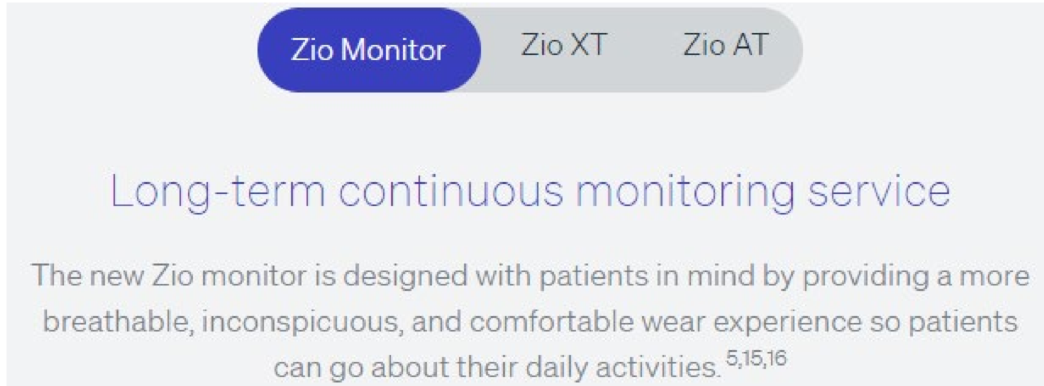
<u>**Claim 1**</u>	<u>**Accused Instrumentalities**</u>
1[e] a first electrocardiographic electrode and a second electrocardiographic electrode,	***The Accused Instrumentalities include a first electrocardiographic electrode and a second electrocardiographic electrode.*** The Zio Monitor satisfies 1[e] because the Zio Monitor includes two elecrocardiographic electrodes labeled in the figure below as "1."  (https://go.irhythmtech.com/hubfs/LB10117.01%20-%20ZIO%20MONITOR%20INSTRUCTIONS%20FOR%20USE%2c%20PRINTED%20(2).pdf)

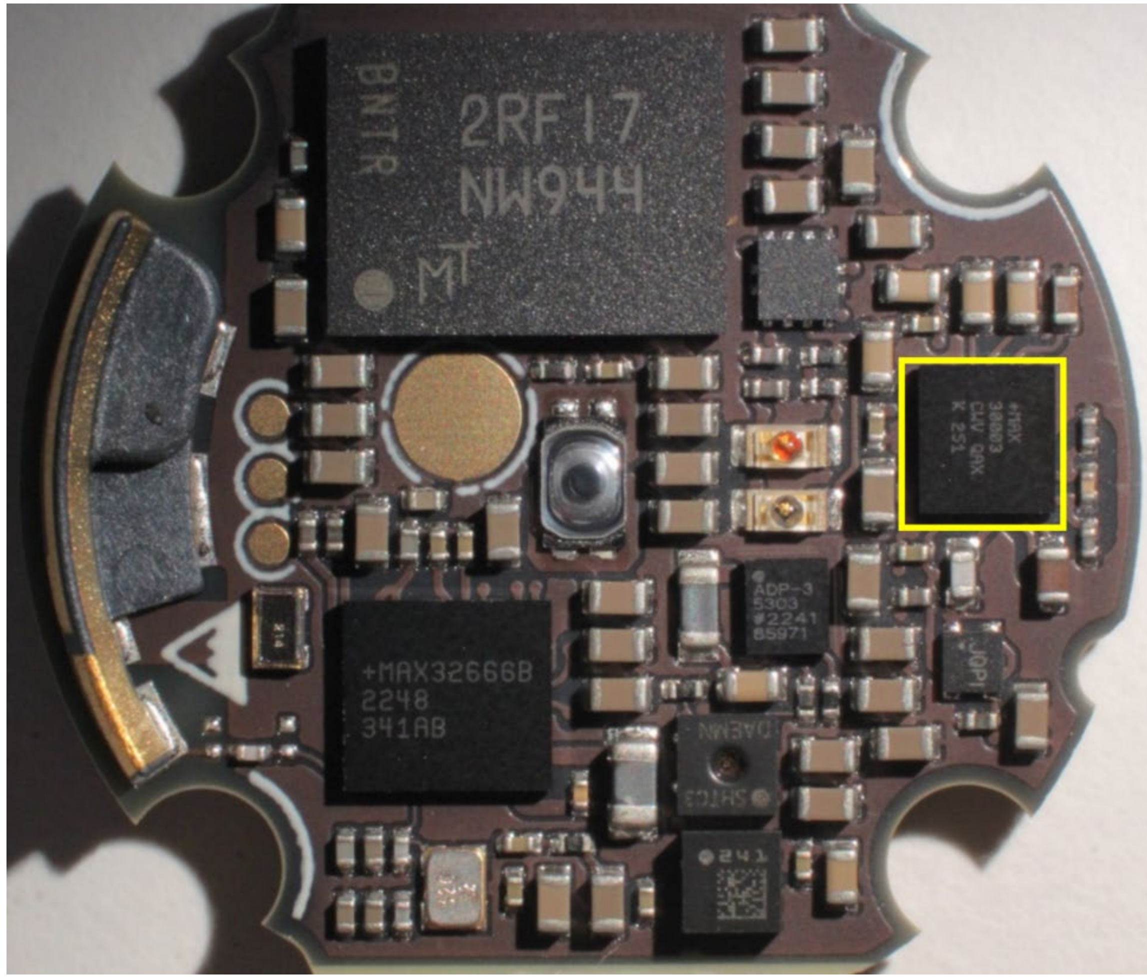
<table>
<tr><th><u>Claim 1</u></th><th><u>Accused Instrumentalities</u></th></tr>
<tr><td>1[f] wherein the first electrocardiographic electrode and the second electrocardiographic electrode are configured to sense electrocardiographic signals,</td><td>The Accused Instrumentalities include wherein the first electrocardiographic electrode and the second electrocardiographic electrode are configured to sense electrocardiographic signals. The Zio Monitor satisfies 1[f] because the Zio Monitor includes two electrocardiographic electrodes that sense electrocardiographic signals.


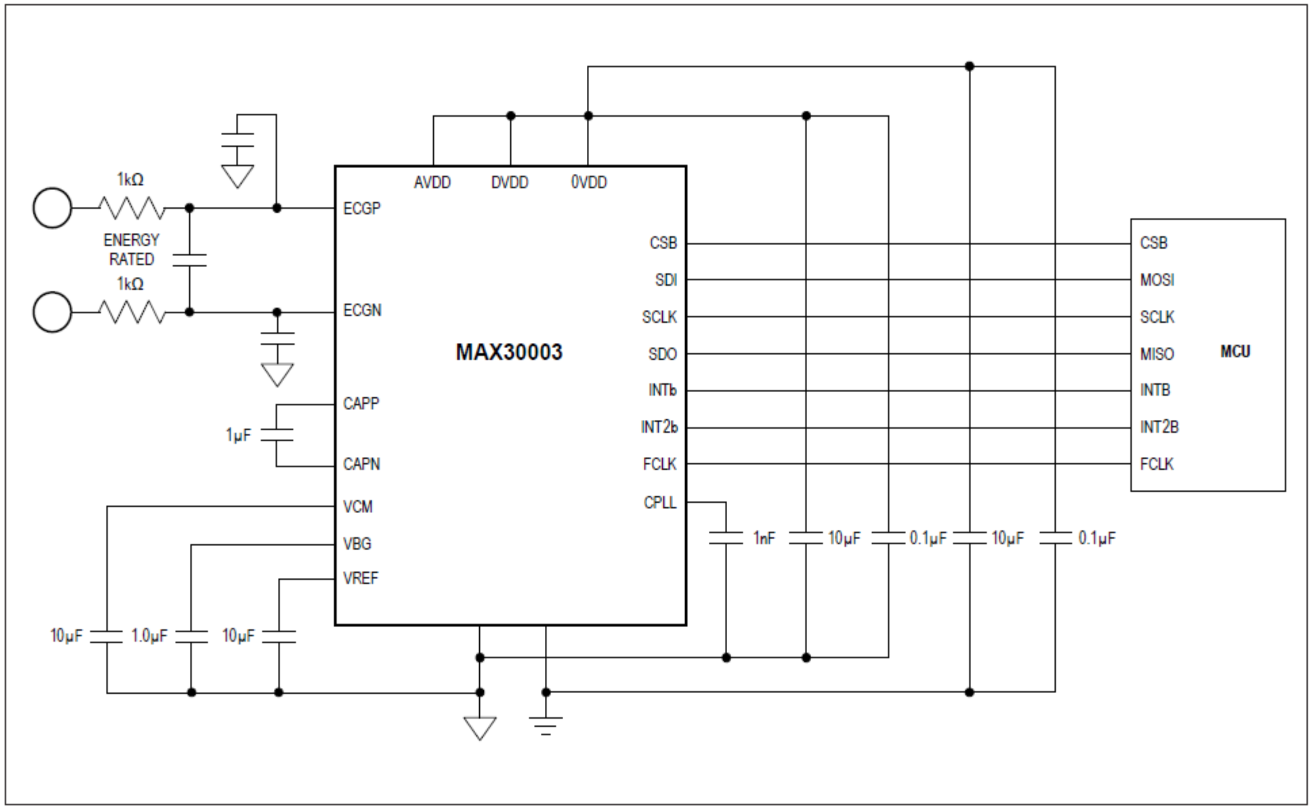
(https://go.irhythmtech.com/hubfs/LB10117.01%20-%20ZIO%20MONITOR%20INSTRUCTIONS%20FOR%20USE%2c%20PRINTED%20(2).pdf)</td></tr>
</table>

Claim 1	Accused Instrumentalities
	The Zio monitor is a single-use ECG monitor that provides a continuous, single-channel recording for up to 14 days. The Zio monitor records ECG data without patient interaction, with the goal of improving patient compliance via simplicity of operation. Patients have the option of pressing a convenient button and filling out a log to document symptomatic events, which will support symptom-rhythm correlation in the diagnostic report. (https://go.irhythmtech.com/hubfs/LB10117.01%20-%20ZIO%20MONITOR%20INSTRUCTIONS%20FOR%20USE%2c%20PRINTED%20(2).pdf) **Intended use** The Zio monitor is intended to capture symptomatic and asymptomatic cardiac events in a continuous electrocardiogram record for long-term monitoring. **Indications for use** The Zio monitor is a prescription-only, single-use ECG monitor that continuously records data for up to 14 days. It is indicated for use on patients who may be asymptomatic or who may suffer from transient symptoms such as palpitations, shortness of breath, dizziness, lightheadedness, pre-syncope, syncope, fatigue, or anxiety. (https://go.irhythmtech.com/hubfs/LB10117.01%20-%20ZIO%20MONITOR%20INSTRUCTIONS%20FOR%20USE%2c%20PRINTED%20(2).pdf)

Claim 1	Accused Instrumentalities
	1. Press the button on your Zio monitor when you feel a symptom. • The light does not flash when the button is pressed. • If you forget to either press the button or log a symptom, the Zio monitor is recording the ECG data. (https://go.irhythmtech.com/hubfs/LB10117.01%20-%20ZIO%20MONITOR%20INSTRUCTIONS%20FOR%20USE%2c%20PRINTED%20(2).pdf) The Zio monitor is an ECG monitor that continuously records the electrical activity of the heart. It is intended to be worn continuously for a time period specified by a provider for up to 14 days. (https://go.irhythmtech.com/hubfs/LB10117.01%20-%20ZIO%20MONITOR%20INSTRUCTIONS%20FOR%20USE%2c%20PRINTED%20(2).pdf)

Claim 1	**Accused Instrumentalities**
	 (https://www.irhythmtech.com/providers/zio-service/zio-monitors)

Claim 1	**Accused Instrumentalities**
	 (Zio Monitor Teardown)

Claim 1	Accused Instrumentalities
	 (MAX30003 Datasheet)

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Claim 1	Accused Instrumentalities
	ANALOG DEVICES Evaluation Kit Available · Design Resources · Tools and Models · Support Click here to ask an associate for production status of specific part numbers. **Ultra-Low Power, Single-Channel Integrated Biopotential (ECG, R-to-R Detection) AFE** **MAX30003** **General Description** The MAX30003 is a complete, biopotential, analog front-end solution for wearable applications. It offers high performance for clinical and fitness applications, with ultra-low power for long battery life. The MAX30003 is a single biopotential channel providing ECG waveforms and heart rate detection. The biopotential channel has ESD protection, EMI filtering, internal lead biasing, DC leads-off detection, ultra-low power leads-on detection during standby mode, and extensive calibration voltages for built-in self-test. Soft power-up sequencing ensures no large transients are injected into the electrodes. The biopotential channel also has high input impedance, low noise, high CMRR, programmable gain, various low-pass and high-pass filter options, and a high resolution analog-to-digital converter. The biopotential channel is DC coupled, can handle large electrode voltage offsets, and has a fast recovery mode to quickly recover from overdrive conditions, such as defibrillation and electrosurgery. The MAX30003 is available in a 28-pin TQFN and 30-bump wafer-level package (WLP), operating over the 0°C to +70°C commercial temperature range. (MAX30003 Datasheet)

Claim 1	Accused Instrumentalities

	Benefits and Features
	• Clinical-Grade ECG AFE with High-Resolution Data Converter
	  • 15.5 Bits Effective Resolution with 5μV_{P-P} Noise
	• Better Dry Starts Due to Much Improved Real World CMRR and High Input Impedance
	  • Fully Differential Input Structure with CMRR > 100dB
	• Offers Better Common-Mode to Differential Mode Conversion Due to High Input Impedance
	  • High Input Impedance > 500MΩ for Extremely Low Common-to-Differential Mode Conversion
	• Minimum Signal Attenuation at the Input During Dry Start Due to High Electrode Impedance
	• High DC Offset Range of ±650mV (1.8V, typ) Allows to Be Used with Wide Variety of Electrodes
	• High AC Dynamic Range of 65mV_{P-P} Will Help the AFE Not Saturate in the Presence of Motion/Direct Electrode Hits
	• Longer Battery Life Compared to Competing Solutions
	  • 85μW at 1.1V Supply Voltage
	• Leads-On Interrupt Feature Allows to Keep μC in Deep Sleep Mode with RTC Off Until Valid Lead Condition is Detected
	  • Lead-On Detect Current: 0.7μA (typ)
	
	(MAX30003 Datasheet)

Claim 1	Accused Instrumentalities
	• Built-In Heart Rate Detection with Interrupt Feature Eliminates the Need to Run HR Algorithm on the µController • Robust R-R Detection in High Motion Environment at Extremely Low Power • Configurable Interrupts Allows the µC Wake-Up Only on Every Heart Beat Reducing the Overall System Power • High Accuracy Allows for More Physiological Data Extractions • 32-Word FIFO Allows You to Wake Up µController Every 256ms with Full ECG Acquisition • High-Speed SPI Interface • Shutdown Current of 0.5µA (typ) (MAX30003 Datasheet) **R-to-R Detection** The MAX30003 contains built-in hardware to detect R-R intervals using an adaptation of the Pan-Tompkins QRS detection algorithm[1]. The timing resolution of the R-R interval is approximately 8ms and depends on the setting of FMSTR [1:0] in CNFG_GEN (0x10) register. See Table 22 for the timing resolution of each setting. (MAX30003 Datasheet)

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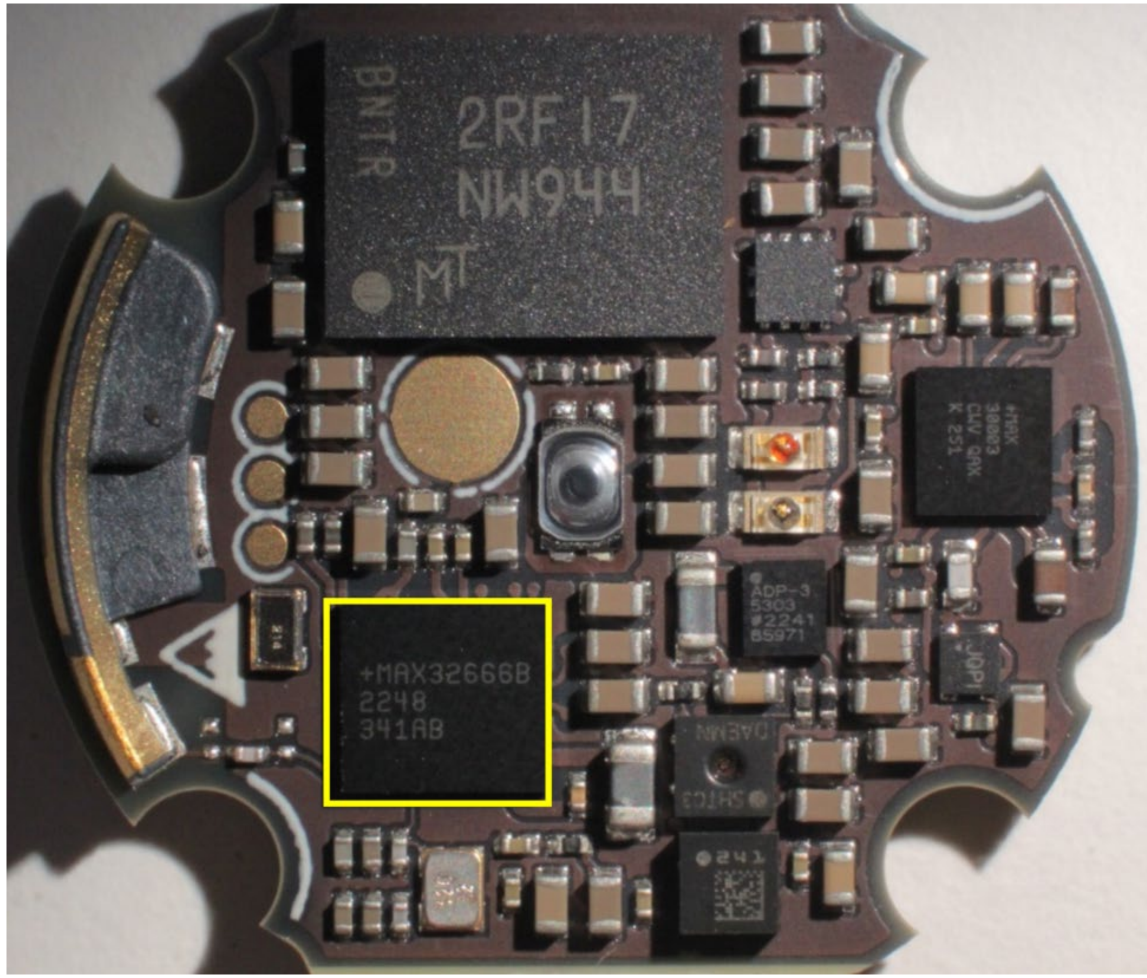
Claim 1	**Accused Instrumentalities**
	 (Zio Monitor Teardown)

Claim 1	Accused Instrumentalities
	ANALOG DEVICES Click here to ask an associate for production status of specific part numbers. MAX32665/MAX32666 Low-Power Arm Cortex-M4 with FPU-Based Microcontroller with Bluetooth 5 for Wearables **General Description** DARWIN is a new breed of low-power microcontrollers built to thrive in the rapidly evolving Internet of Things (IoT). They are smart, with the biggest memories in their class and a massively scalable memory architecture. They run forever, thanks to wearable-grade power technology. They are durable enough to withstand the most advanced cyberattacks. DARWIN microcontrollers are designed to run any application imaginable—in places where you would not dream of sending other microcontrollers. Generation UB microcontrollers are designed to handle the increasingly complex applications demanded by today's advanced battery-powered devices and wirelessly connected devices, while providing robust hardware security and Bluetooth® 5 Low Energy (Bluetooth LE) radio connectivity. The MAX32665/MAX32666 UB class microcontrollers are advanced systems-on-chips featuring an Arm® Cortex®-M4 with FPU CPU for efficient computation of complex functions and algorithms with integrated power management. It also includes the newest generation Bluetooth 5 LE radio with support for long range (4x) and high throughput (2Mbps) and ADI's best-in-class hardware security suite trust protection unit (TPU). The devices offer large on-board memory with 1MB flash and 560KB SRAM. Split flash banks of 512KB each support seamless over-the-air upgrades, adding an additional degree of reliability. Memory scalability of data (SRAM) and code (Flash) space is supported by two SPI execute-in-place (SPIX) interfaces. (MAX32666 Datasheet)

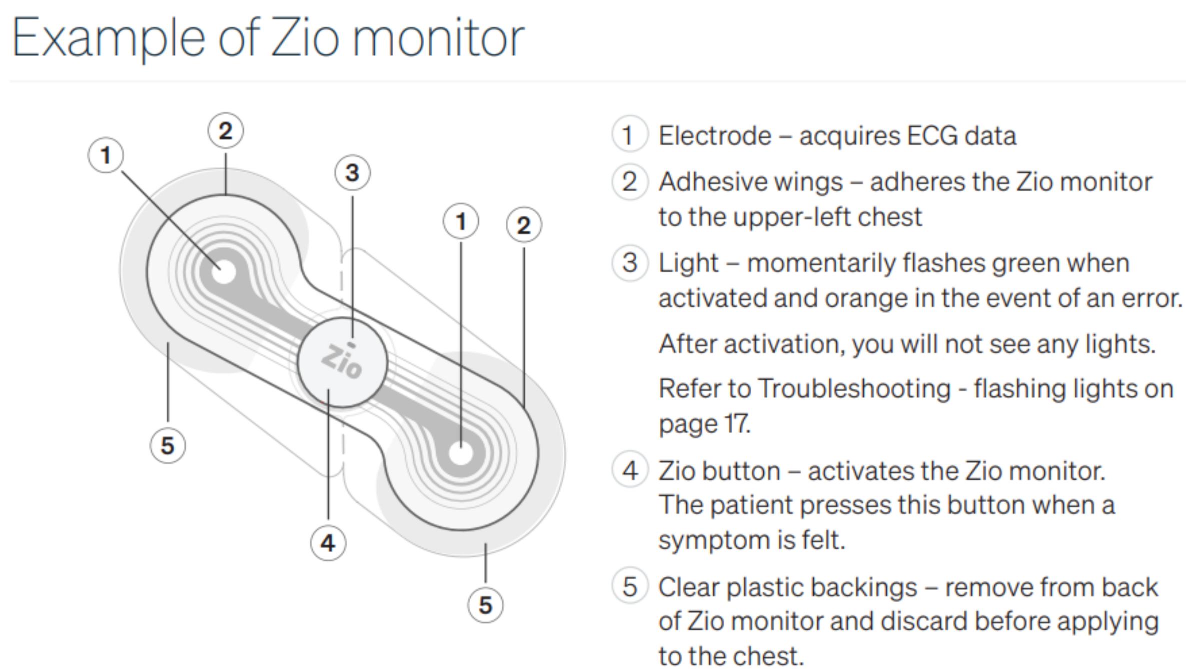
Claim 1	Accused Instrumentalities

	Multiple high-speed interfaces are supported including HS-USB, secure digital interface (SD, SDIO, MMC, SD-HC, and microSD™), SPI, UART, and I^2C serial interfaces, and an audio subsystem supporting PDM, PCM, I^2S, and TDM interfaces. An 8-input, 10-bit ADC is available to monitor analog inputs from external sensors and meters. The devices are available in 109-bump WLP (0.35mm pitch) and 121-bump CTBGA (0.65mm pitch).
	
	Applications
	• Connected Home
	• Industrial Sensors
	• Payment/Fitness/Medical Wearables
	• Telemedicine
	• Gaming Devices
	• Hearables
	
	(MAX32666 Datasheet)
	
	Benefits and Features
	• High-Efficiency Microcontroller and Audio DSP for Wearable and Hearable Devices
	  • Arm Cortex-M4 with FPU Up to 96MHz
	  • Optional Second Arm Cortex-M4 with FPU Optimized for Data Processing
	  • Low-Power, 7.3728MHz System Clock Option
	  • 1MB Flash, Organized into Dual Banks 2 x 512KB
	  • 560KB SRAM; 3 x 16KB Cache
	• Bluetooth 5 Low Energy Radio
	  • 1Mbps and 2Mbps Data Throughput
	  • Long Range (125kbps and 500kbps)
	  • Advertising Extension
	  • Rx Sensitivity: -95dbm; Tx Power Up to +4.5dbm
	  • On-Chip Matching with Single-Ended Antenna Port
	
	(MAX32666 Datasheet)

Claim 1	Accused Instrumentalities
	MAX32665/MAX32666 The MAX32665/MAX32666 are Arm Cortex-M4 with FPU-based microcontrollers with 1MB flash and 560KB SRAM. They are ideal for wearable medical fitness applications. A second Arm Cortex-M4 with FPU supporting ROM and cache supports extended data processing capabilities such as audio processing for wireless Bluetooth applications. The architecture includes a Bluetooth 5 Low Energy radio. The devices feature five powerful and flexible power modes. The flash memory is split into two banks of 512KB to provide flexibility when programming over the air. A built-in single inductor multiple output (SIMO) switch mode power supply allows the device to be optionally self-powered by a primary lithium cell. Dedicated hardware runs the Bluetooth 5 Low Energy stack freeing the CPUs for data processing tasks. Built-in dynamic clock gating and firmware-controlled power gating allow the user to optimize power for the specific application. Multiple SPI, UART, and I^2C serial interfaces, 1-Wire Master, and USB 2.0 High-Speed Device interface allow interconnection to a wide variety of external sensors. An audio subsystem supports PDM, PCM, I^2S, and TDM. An 8-input, 10-bit ADC is available to monitor analog input from external sensors and meters. The MAX32666 incorporates a trust protection unit (TPU) with encryption and advanced security features. These features include a modular arithmetic accelerator (MAA) for fast ECDSA, a hardware AES engine, a hardware TRNG entropy generator, a SHA-2 accelerator, and a secure bootloader. All devices are available in a 109-bump WLP with 0.35mm pitch and a 121-bump CTBGA with 0.65mm pitch packages. (MAX32666 Datasheet) **Arm Cortex-M4 with FPU Processor** The Arm Cortex-M4 with FPU processors CPU0 and CPU1 are ideal for the emerging category of wearable medical and wellness applications. The architecture combines high-efficiency signal processing functionality with low power, low cost, and ease of use. The Arm Cortex-M4 with FPU DSP supports single instruction multiple data (SIMD) path DSP extensions, providing: • Four parallel 8-bit add/sub • Floating point single precision • Two parallel 16-bit add/sub • Two parallel MACs • 32- or 64-bit accumulate • Signed, unsigned, data with or without saturation (MAX32666 Datasheet)

<table>
<tr><th><u>Claim 1</u></th><th><u>Accused Instrumentalities</u></th></tr>
<tr><td>1[g] wherein the first electrocardiographic electrode and the second electrocardiographic electrode are coupled to the flexible circuit,</td><td>

The Accused Instrumentalities include wherein the first electrocardiographic electrode and the second electrocardiographic electrode are coupled to the flexible circuit. The Zio Monitor satisfies 1[g] because the Zio Monitor has electrocardiographic electrodes that are coupled to the flexible circuit.



(https://go.irhythmtech.com/hubfs/LB10117.01%20-%20ZIO%20MONITOR%20INSTRUCTIONS%20FOR%20USE%2c%20PRINTED%20(2).pdf)

</td></tr>
</table>

Claim 1	Accused Instrumentalities
	 Zio Monitor (https://s201.q4cdn.com/653785554/files/doc_downloads/V4_-_iRhythm_ESG_Report_2023.pdf)  (Zio Monitor Teardown)

Claim 1	**Accused Instrumentalities**
	 (Zio Monitor Teardown)

Claim 1	Accused Instrumentalities
	 (Zio Monitor Teardown)

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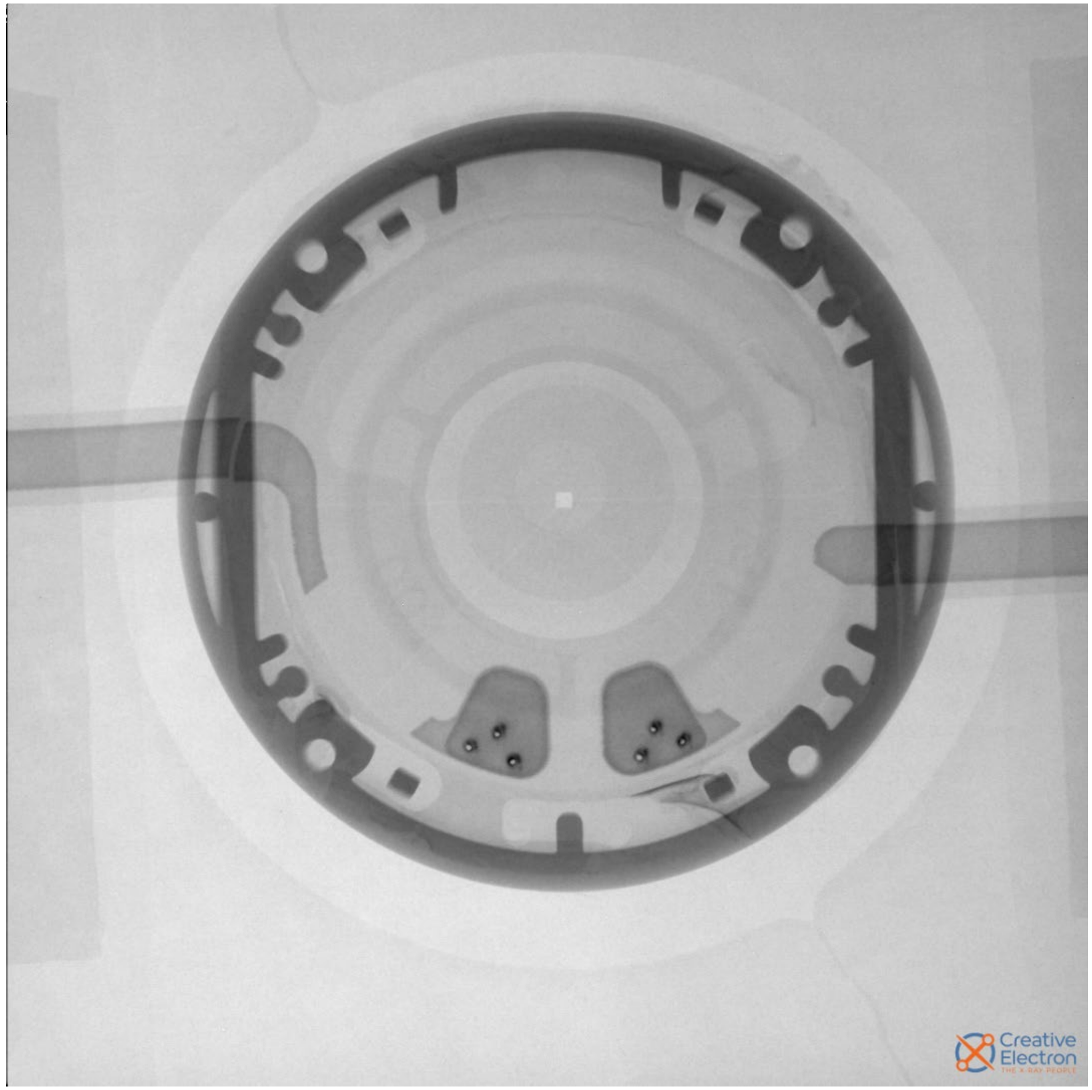
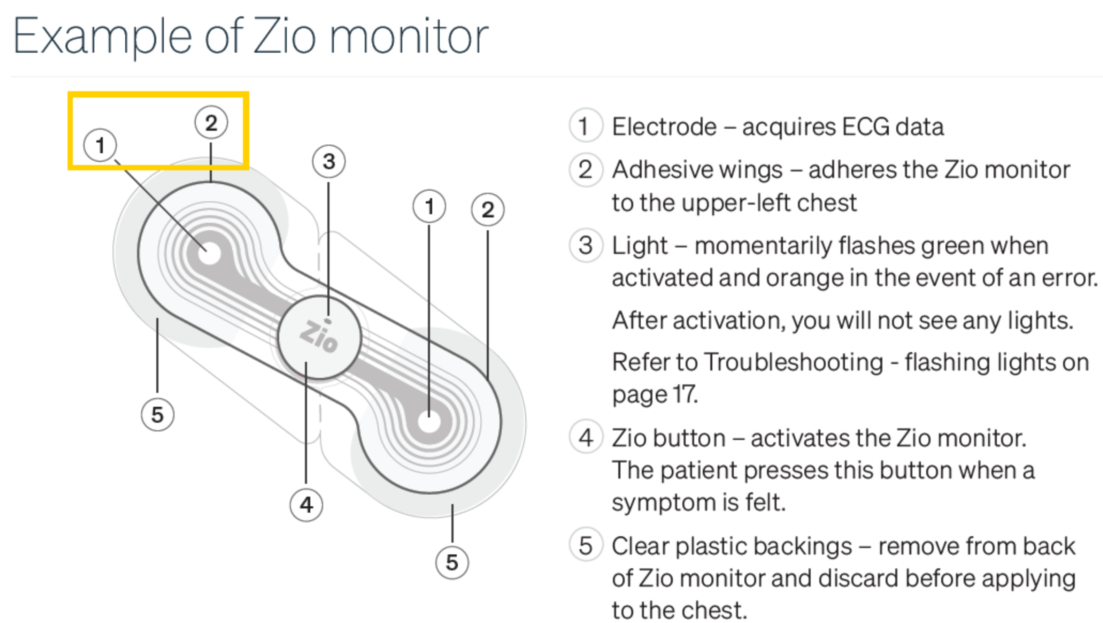
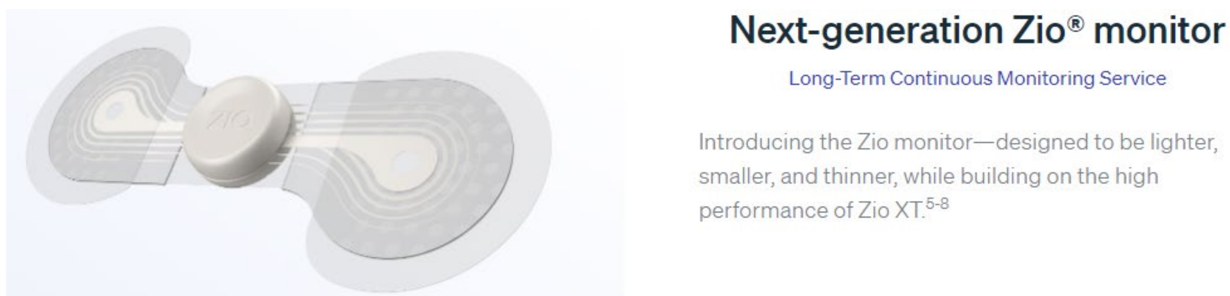
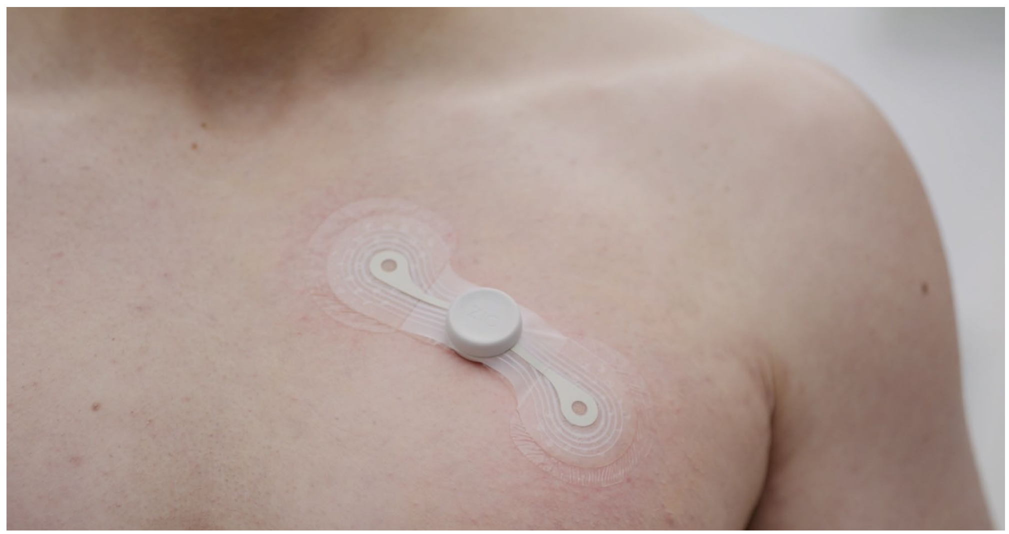
Claim 1	Accused Instrumentalities
	 (Zio Monitor Teardown)

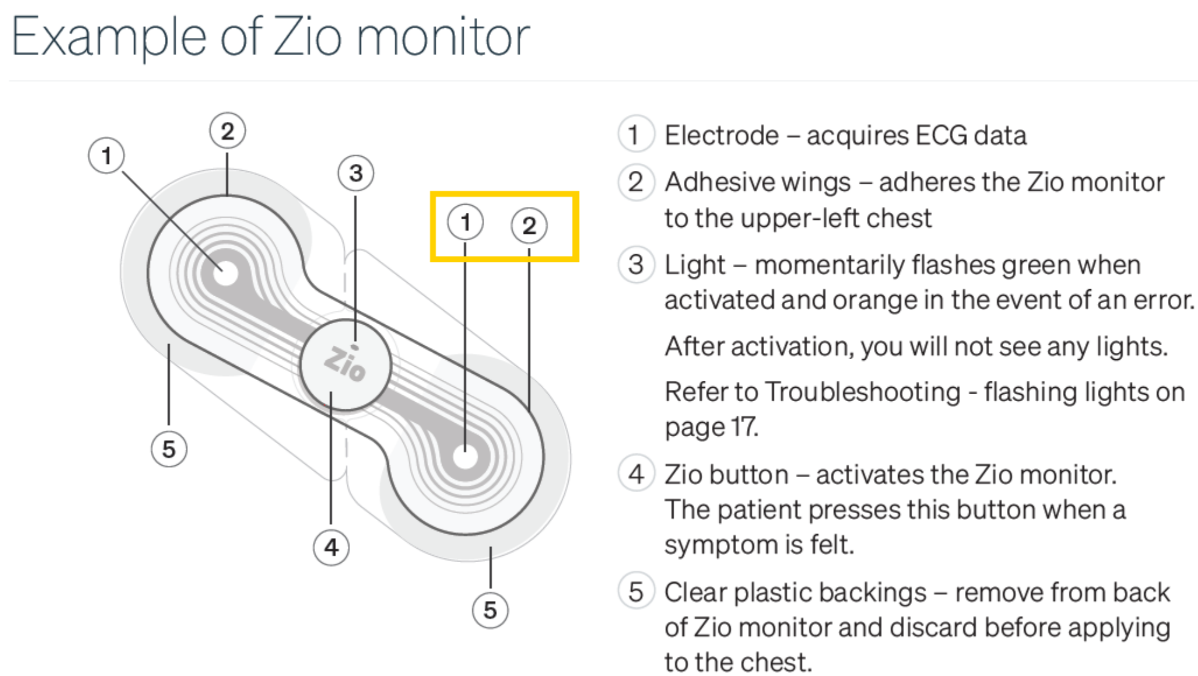
Claim 1	Accused Instrumentalities
	 (Zio Monitor Teardown)  (Zio Monitor Teardown)

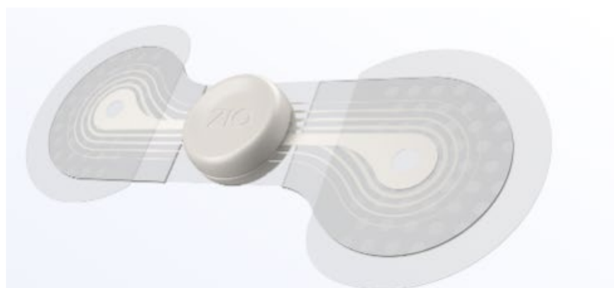
<u>Claim 1</u>	**<u>Accused Instrumentalities</u>**
1[h] wherein the first electrocardiographic electrode is conductively exposed at the first face along the first end section of the strip,	***The Accused Instrumentalities include wherein the first electrocardiographic electrode is conductively exposed at the first face along the first end section of the strip.*** The Zio Monitor satisfies 1[h] because the Zio Monitor includes an electrocardiographic electrode conductively exposed on the upper side (i.e., the first face) along one end (i.e., the first end section) of the strip.  (https://go.irhythmtech.com/hubfs/LB10117.01%20-%20ZIO%20MONITOR%20INSTRUCTIONS%20FOR%20USE%2c%20PRINTED%20(2).pdf)

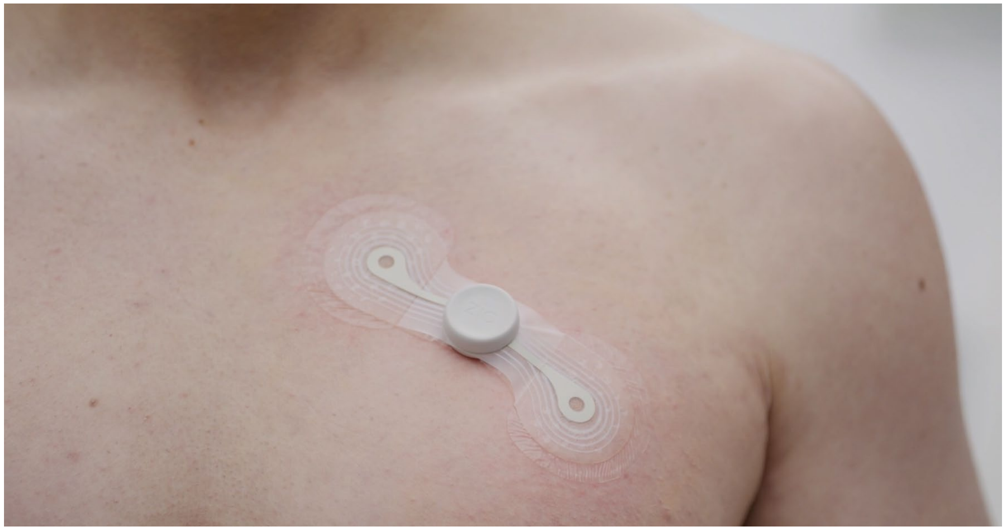
Claim 1	**Accused Instrumentalities**
	 Zio Monitor (https://s201.q4cdn.com/653785554/files/doc_downloads/V4_-_iRhythm_ESG_Report_2023.pdf) The Zio patches include the following features: • patented flexible, lightweight, wire-free design; • unobtrusive and inconspicuous profile; • proprietary adhesive backing designed to keep the Zio patch securely in place for the duration of the prescribed wear period; (https://s201.q4cdn.com/653785554/files/doc_downloads/V4_-_iRhythm_ESG_Report_2023.pdf)

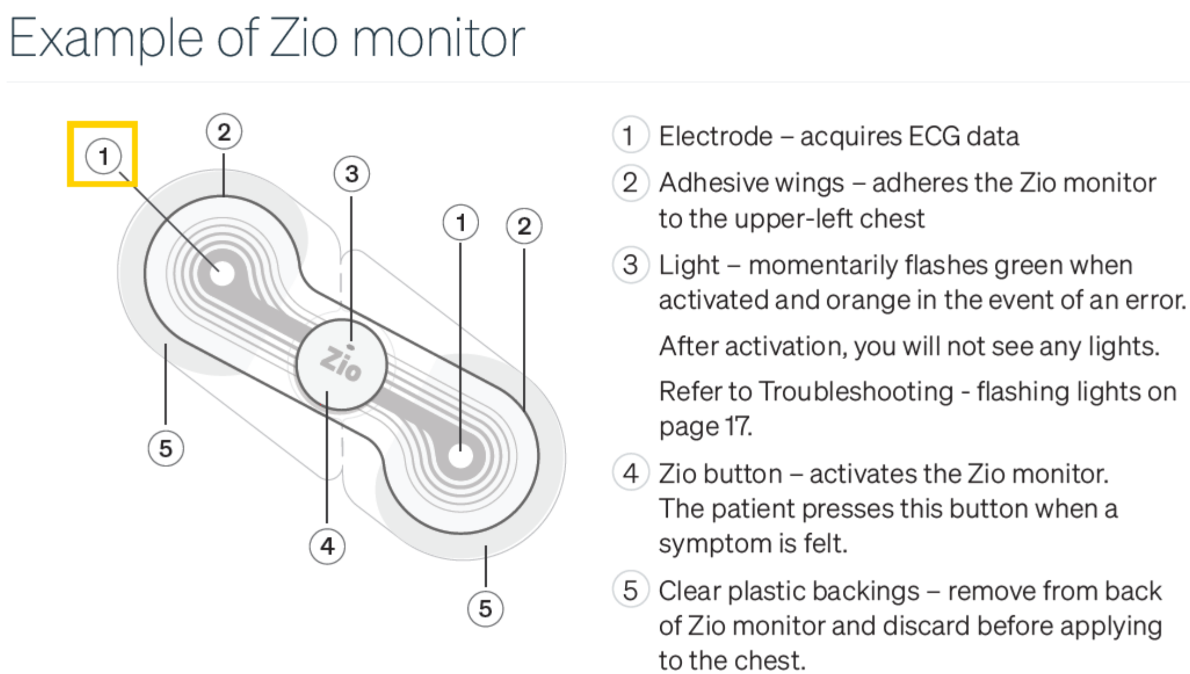
<u>Claim 1</u>	**<u>Accused Instrumentalities</u>**
	 (https://www.irhythmtech.com/providers/zio-service/zio-monitors)  (https://vimeo.com/861741895?)

Claim 1	Accused Instrumentalities
	 (Zio Monitor Teardown)

Claim 1	**Accused Instrumentalities**
1[i] wherein the second electrocardiographic electrode is conductively exposed at the first face along the second end section of the strip,	***The Accused Instrumentalities include wherein the second electrocardiographic electrode is conductively exposed at the first face along the second end section of the strip.*** The Zio Monitor satisfies 1[i] because the Zio Monitor includes an electrocardiographic electrode conductively exposed on the upper side (i.e., the first face) along one end (i.e., the second end section) of the strip.  (https://go.irhythmtech.com/hubfs/LB10117.01%20-%20ZIO%20MONITOR%20INSTRUCTIONS%20FOR%20USE%2c%20PRINTED%20(2).pdf)

Claim 1	**Accused Instrumentalities**
	The Zio patches include the following features: • patented flexible, lightweight, wire-free design; • unobtrusive and inconspicuous profile; • proprietary adhesive backing designed to keep the Zio patch securely in place for the duration of the prescribed wear period; (https://s201.q4cdn.com/653785554/files/doc_downloads/V4_-_iRhythm_ESG_Report_2023.pdf)  **Next-generation Zio® monitor** Long-Term Continuous Monitoring Service Introducing the Zio monitor—designed to be lighter, smaller, and thinner, while building on the high performance of Zio XT.[5-8] (https://www.irhythmtech.com/providers/zio-service/zio-monitors)

<u>**Claim 1**</u>	<u>**Accused Instrumentalities**</u>
	 (https://vimeo.com/861741895?)  (Zio Monitor Teardown)

Claim 1	Accused Instrumentalities
1[j] wherein the first circuit trace is electrically coupled to the first electrocardiographic electrode,	***The Accused Instrumentalities include wherein the first circuit trace is electrically coupled to the first electrocardiographic electrode.*** The Zio Monitor satisfies 1[j] because the Zio Monitor includes circuit traces, one of which is electrically coupled to one of the electrocardiographic electrodes (i.e., the first electrocardiographic electrode).  (https://go.irhythmtech.com/hubfs/LB10117.01%20-%20ZIO%20MONITOR%20INSTRUCTIONS%20FOR%20USE%2c%20PRINTED%20(2).pdf)

Claim 1	Accused Instrumentalities
	 Zio Monitor (https://s201.q4cdn.com/653785554/files/doc_downloads/V4_-_iRhythm_ESG_Report_2023.pdf)

Claim 1	**Accused Instrumentalities**
	Day: From a technical viewpoint what we did was really to leverage a lot of advances not just in microprocessor efficiency, which is certainly part of it in terms of miniaturization as well as energy efficiency, but also we really challenged ourselves to figure out how to effectively fit in the smallest possible form factor, which for us was motivated a lot by the size of our battery, which is just a standard, easily available, and fortunately easily recyclable coin cell battery. We challenged ourselves to figure out how to miniaturize the device down to the level of one of those coin cells instead of the two that the Zio XT device uses. And that became feasible by the advances in microelectronic microprocessor efficiency and size as well through its miniaturization. But it also required a lot of really complicated dynamics from an electrical engineering perspective to figure out how to get all the components of a wearable medical device and a biosensor onto that small form factor. So, miniaturization was focused on very clever ways of handling some of the larger components, which for example involved moving some of the big resistors that are required on the device to the more flexible part of the patch instead of on the actual printed circuit board in the housing. And this is a patented feature that we've already received a patent on it and we're pursuing more around it, but it was the idea that these three big resistors are not too big in terms of the homage that they have but also in terms of the size that they are. So, if you put them on the circuit board, they are these pretty big components, so we realized pretty early on that we couldn't really do that and still fit the design constraints. So, we innovated a different way, which was to integrate it into the ECG tracings themselves. (https://www.mddionline.com/cardiovascular/behind-the-design-how-irhythm-built-its-new-zio-monitor)

Claim 1	**Accused Instrumentalities**
	 (Zio Monitor Teardown)  (Zio Monitor Teardown)

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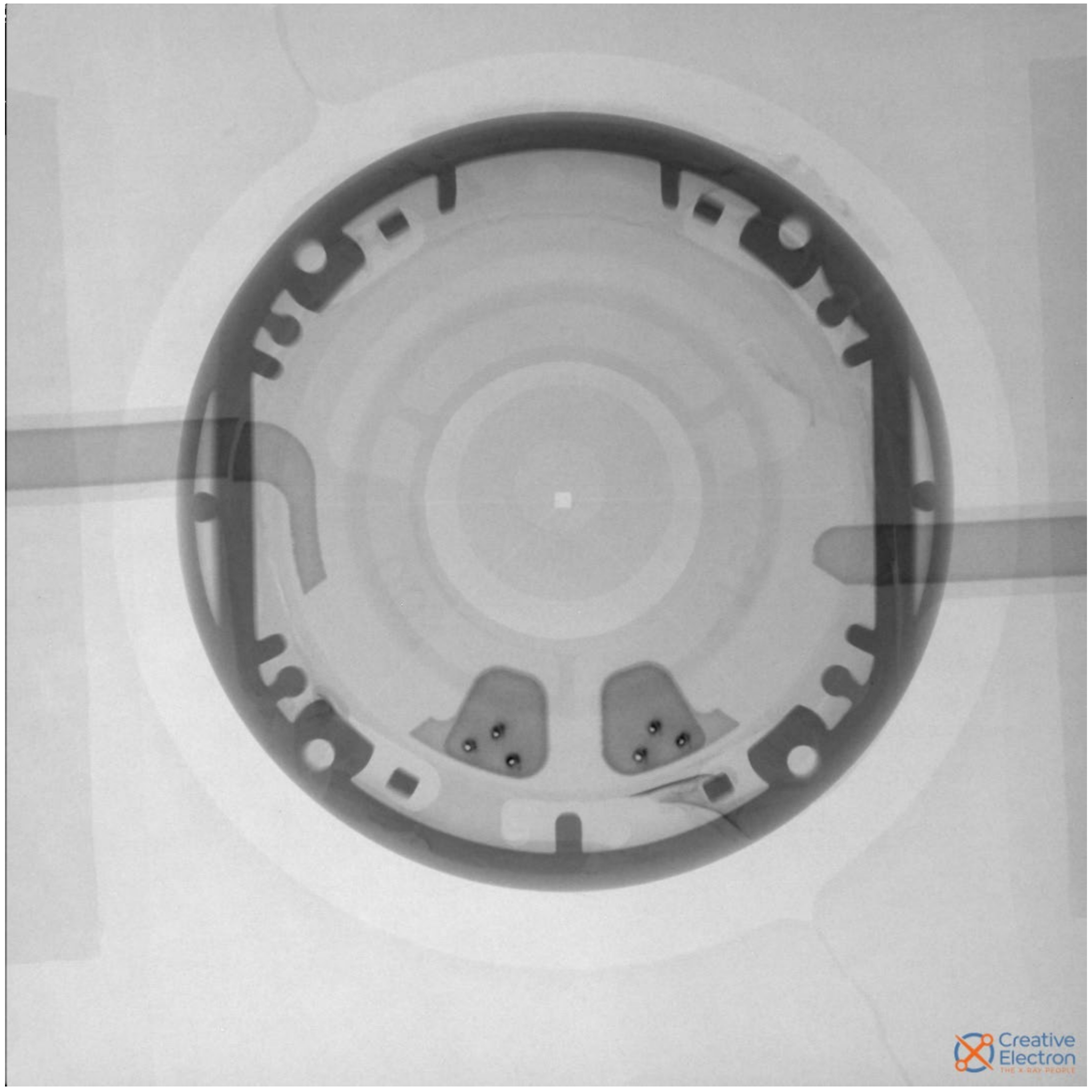
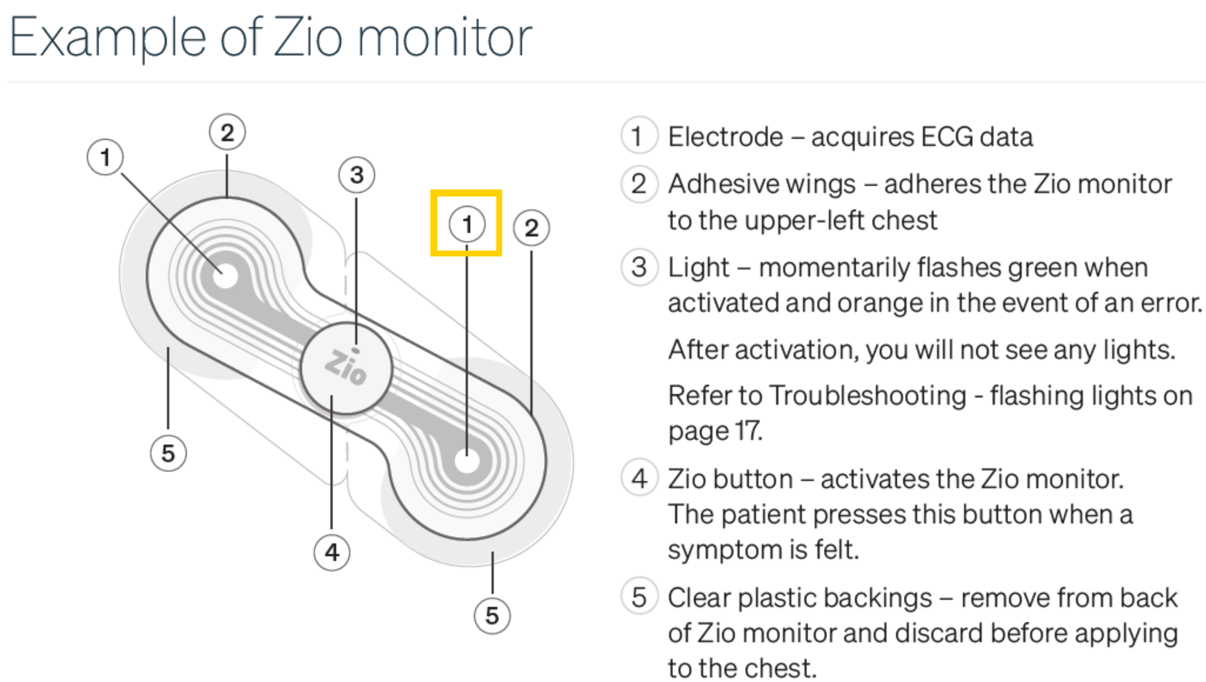
Claim 1	**Accused Instrumentalities**
	 (Zio Monitor Teardown)

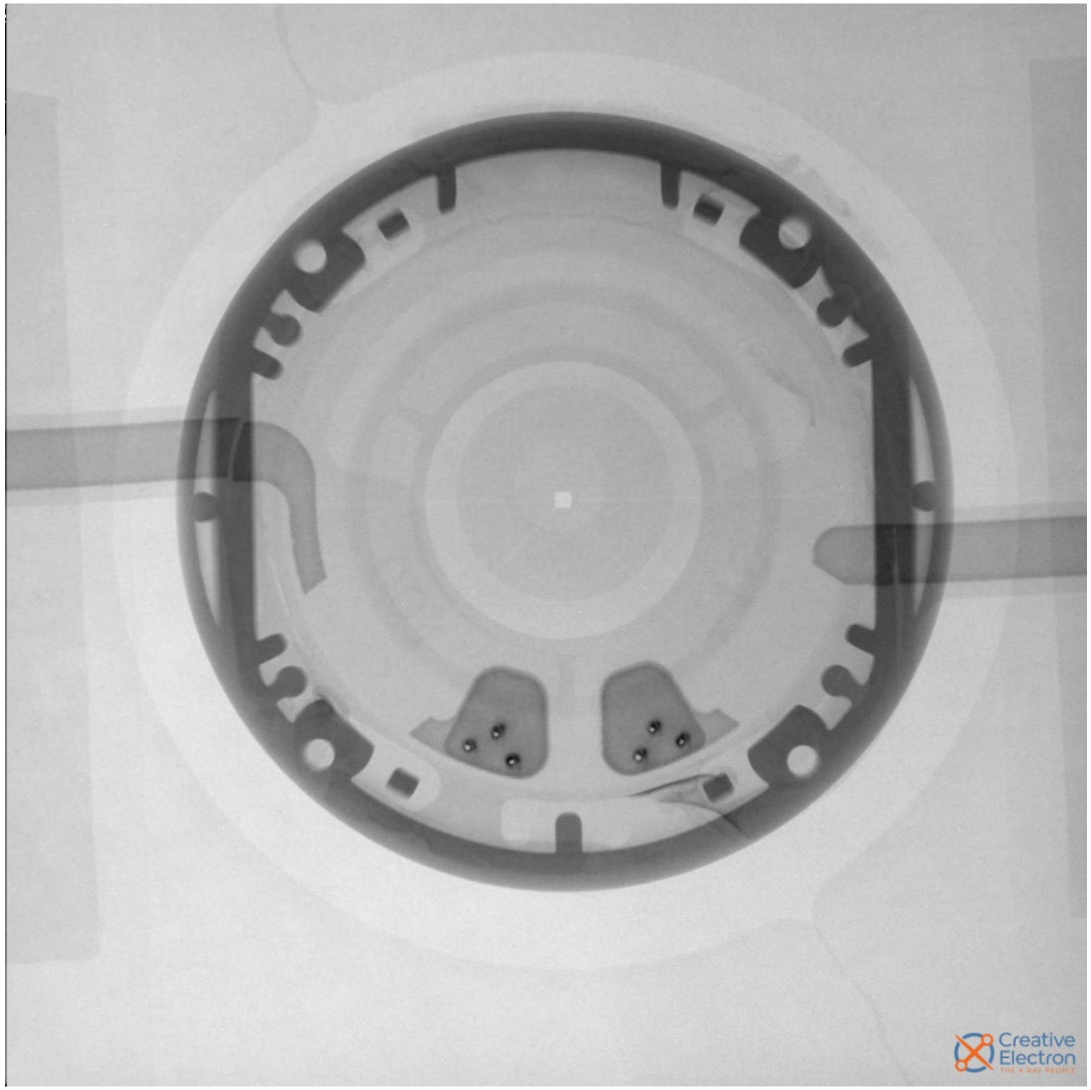
Claim 1	**Accused Instrumentalities**
	 (Zio Monitor Teardown)

Claim 1	Accused Instrumentalities
	 (Zio Monitor Teardown)  (Zio Monitor Teardown)

<u>Claim 1</u>	<u>Accused Instrumentalities</u>
1[k] wherein the second circuit trace is electrically coupled to the second electrocardiographic electrode, and	***The Accused Instrumentalities include wherein the second circuit trace is electrically coupled to the second electrocardiographic electrode.*** The Zio Monitor satisfies 1[k] because the Zio Monitor includes circuit traces, one of which is coupled to one of the electrocardiographic electrodes (i.e., the second electrocardiographic electrode).  (https://go.irhythmtech.com/hubfs/LB10117.01%20-%20ZIO%20MONITOR%20INSTRUCTIONS%20FOR%20USE%2c%20PRINTED%20(2).pdf)

Claim 1	**Accused Instrumentalities**
	 (Zio Monitor Teardown)  (Zio Monitor Teardown)

Claim 1	**Accused Instrumentalities**
	 (Zio Monitor Teardown)

Claim 1	Accused Instrumentalities
	 (Zio Monitor Teardown)

Claim 1	Accused Instrumentalities
	 (Zio Monitor Teardown)  (Zio Monitor Teardown)

Claim 1	**Accused Instrumentalities**
	Day: From a technical viewpoint what we did was really to leverage a lot of advances not just in microprocessor efficiency, which is certainly part of it in terms of miniaturization as well as energy efficiency, but also we really challenged ourselves to figure out how to effectively fit in the smallest possible form factor, which for us was motivated a lot by the size of our battery, which is just a standard, easily available, and fortunately easily recyclable coin cell battery. We challenged ourselves to figure out how to miniaturize the device down to the level of one of those coin cells instead of the two that the Zio XT device uses. And that became feasible by the advances in microelectronic microprocessor efficiency and size as well through its miniaturization. But it also required a lot of really complicated dynamics from an electrical engineering perspective to figure out how to get all the components of a wearable medical device and a biosensor onto that small form factor. So, miniaturization was focused on very clever ways of handling some of the larger components, which for example involved moving some of the big resistors that are required on the device to the more flexible part of the patch instead of on the actual printed circuit board in the housing. And this is a patented feature that we've already received a patent on it and we're pursuing more around it, but it was the idea that these three big resistors are not too big in terms of the homage that they have but also in terms of the size that they are. So, if you put them on the circuit board, they are these pretty big components, so we realized pretty early on that we couldn't really do that and still fit the design constraints. So, we innovated a different way, which was to integrate it into the ECG tracings themselves. (https://www.mddionline.com/cardiovascular/behind-the-design-how-irhythm-built-its-new-zio-monitor)

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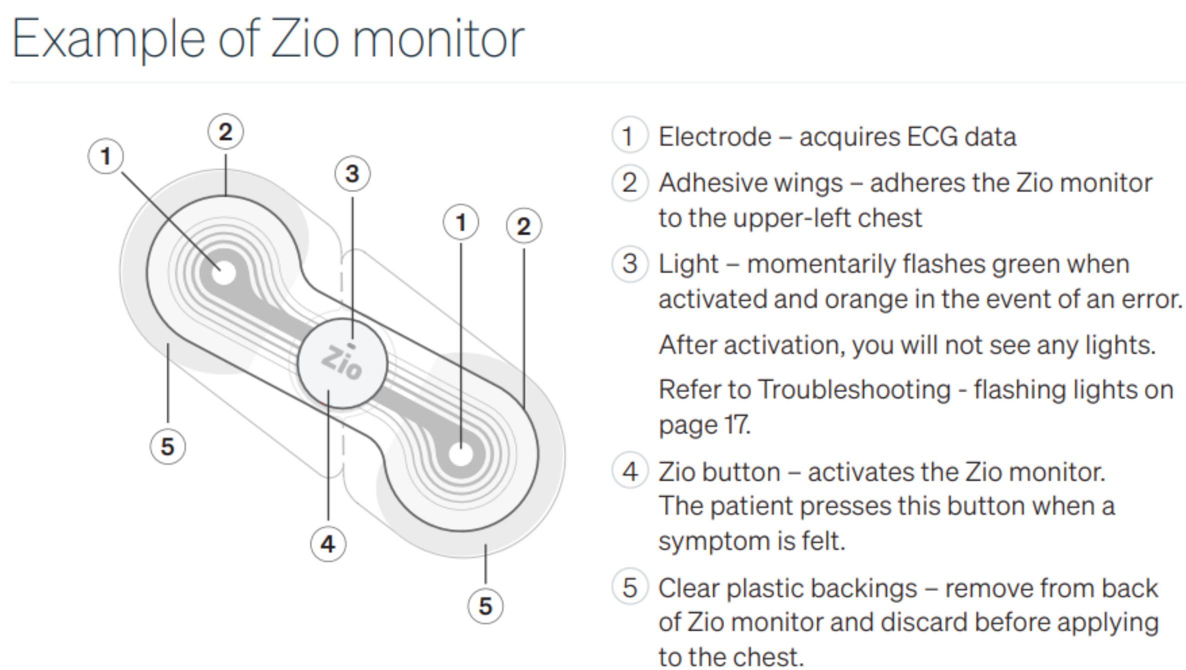
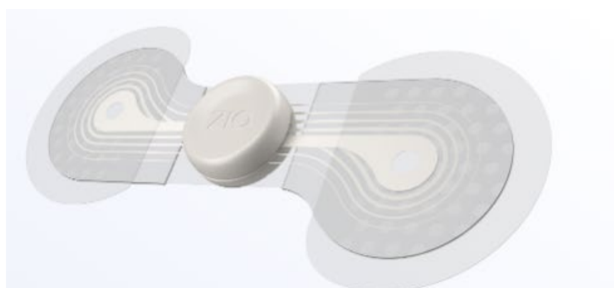
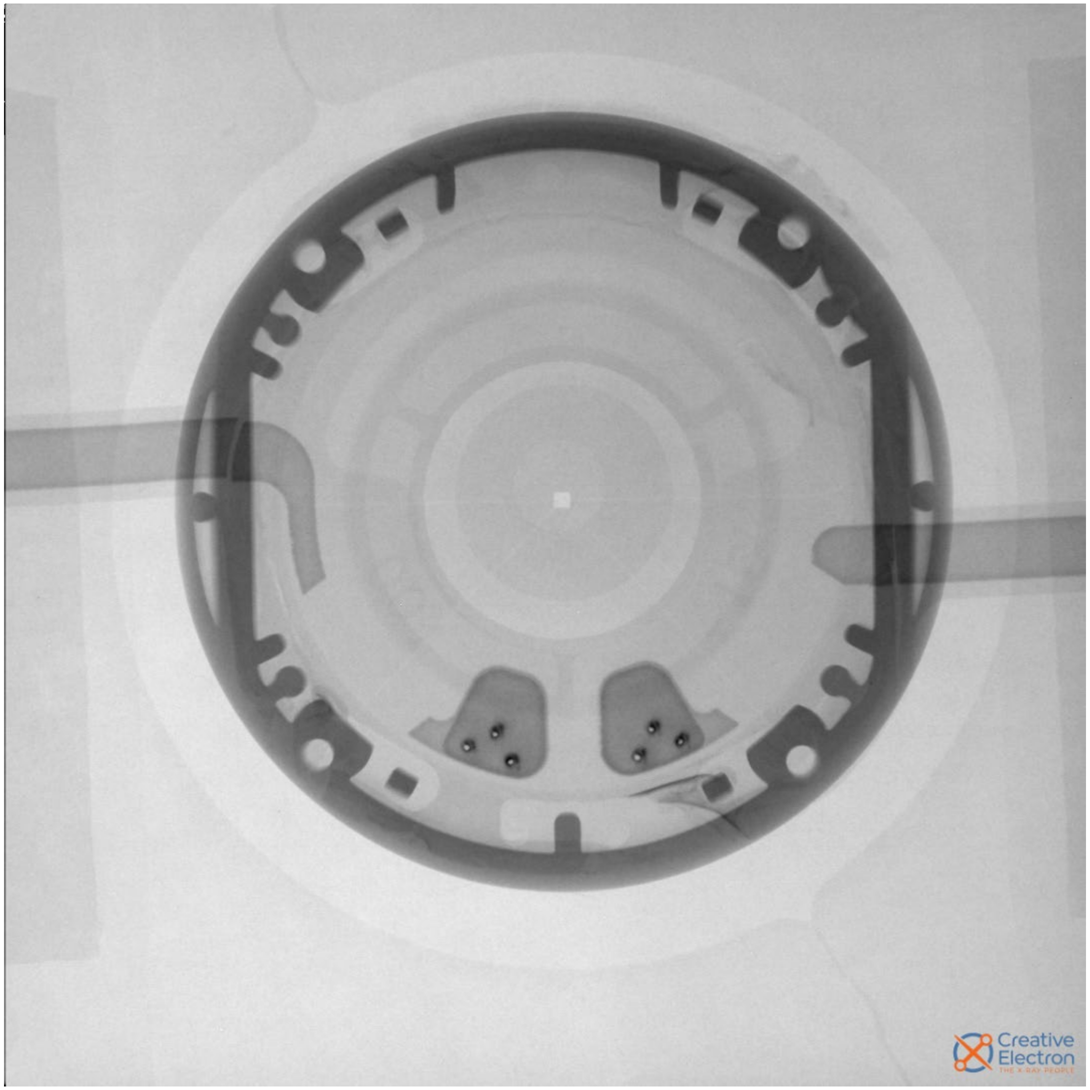
Claim 1	Accused Instrumentalities
1[l] wherein the first electrocardiographic electrode includes an inline resistor;	***The Accused Instrumentalities include wherein the first electrocardiographic electrode includes an inline resistor.*** The Zio Monitor satisfies 1[l] because the Zio Monitor includes an inline resistor located on the flexible backing. Further, the inline resister is integrated into the ECG tracings.  (https://go.irhythmtech.com/hubfs/LB10117.01%20-%20ZIO%20MONITOR%20INSTRUCTIONS%20FOR%20USE%2c%20PRINTED%20(2).pdf)

Claim 1	Accused Instrumentalities
	 Zio Monitor (https://s201.q4cdn.com/653785554/files/doc_downloads/V4_-_iRhythm_ESG_Report_2023.pdf)  **Next-generation Zio® monitor** Long-Term Continuous Monitoring Service Introducing the Zio monitor—designed to be lighter, smaller, and thinner, while building on the high performance of Zio XT.[5-8] (https://www.irhythmtech.com/providers/zio-service/zio-monitors)

Claim 1	Accused Instrumentalities
	Day: From a technical viewpoint what we did was really to leverage a lot of advances not just in microprocessor efficiency, which is certainly part of it in terms of miniaturization as well as energy efficiency, but also we really challenged ourselves to figure out how to effectively fit in the smallest possible form factor, which for us was motivated a lot by the size of our battery, which is just a standard, easily available, and fortunately easily recyclable coin cell battery. We challenged ourselves to figure out how to miniaturize the device down to the level of one of those coin cells instead of the two that the Zio XT device uses. And that became feasible by the advances in microelectronic microprocessor efficiency and size as well through its miniaturization. But it also required a lot of really complicated dynamics from an electrical engineering perspective to figure out how to get all the components of a wearable medical device and a biosensor onto that small form factor. So, miniaturization was focused on very clever ways of handling some of the larger components, which for example involved moving some of the big resistors that are required on the device to the more flexible part of the patch instead of on the actual printed circuit board in the housing. And this is a patented feature that we've already received a patent on it and we're pursuing more around it, but it was the idea that these three big resistors are not too big in terms of the homage that they have but also in terms of the size that they are. So, if you put them on the circuit board, they are these pretty big components, so we realized pretty early on that we couldn't really do that and still fit the design constraints. So, we innovated a different way, which was to integrate it into the ECG tracings themselves. (https://www.mddionline.com/cardiovascular/behind-the-design-how-irhythm-built-its-new-zio-monitor)

Claim 1	Accused Instrumentalities
	 (Zio Monitor Teardown)  (Zio Monitor Teardown)

Claim 1	Accused Instrumentalities
	 (Zio Monitor Teardown)

Claim 1	Accused Instrumentalities
	(Zio Monitor Teardown)

Claim 1	Accused Instrumentalities
	 (Zio Monitor Teardown)  (Zio Monitor Teardown)

Claim 1	Accused Instrumentalities
1[m] a battery vertically aligned with a sealed housing,	***The Accused Instrumentalities include a battery vertically aligned with a sealed housing.*** The Zio Monitor satisfies 1[m] because the Zio Monitor includes a battery. The battery powers the body worn device. The battery is located in and vertically aligned with a sealed housing. **Power specifications** Battery type: 1 lithium manganese dioxide coin cell Battery life: > 14 days (https://go.irhythmtech.com/hubfs/LB10117.01%20-%20ZIO%20MONITOR%20INSTRUCTIONS%20FOR%20USE%2c%20PRINTED%20(2).pdf) **Precautions** • During storage and prior to prescription for a patient, do not exceed the temperature and humidity limitations for the Zio monitor. Devices exposed to environmental conditions outside the specified range may have degraded adhesive and battery performance. • Observe the temperature and humidity specifications for transportation and storage listed on the box and in the instructions for use. • Confirm the expiration date for the Zio monitor listed on the Zio box or pouch. Use of an expired device may cause a degradation of ECG signal quality and a low battery condition. Apply the device on or before expiration date. (https://go.irhythmtech.com/hubfs/LB10117.01%20-%20ZIO%20MONITOR%20INSTRUCTIONS%20FOR%20USE%2c%20PRINTED%20(2).pdf)

Claim 1	Accused Instrumentalities
	The Zio patches include the following features: • patented flexible, lightweight, wire-free design; • unobtrusive and inconspicuous profile; • proprietary adhesive backing designed to keep the Zio patch securely in place for the duration of the prescribed wear period; • water-resistant functionality, allowing patients to shower, sleep, and perform normal daily activities, including moderate exercise; • hydrogel electrodes and a compliant mechanical design to deliver a clear ECG with minimal artifact from movement; • large symptom button, or patient trigger, that is easy to find and press; • indicated single application wear period of up to 14 days (for longer prescribed wear periods for MCT services, additional Zio AT patches and gateways will be provided); and • sufficient battery power for the entire wear period, without the need to recharge or replace batteries. (https://s201.q4cdn.com/653785554/files/doc_downloads/V4_-_iRhythm_ESG_Report_2023.pdf)

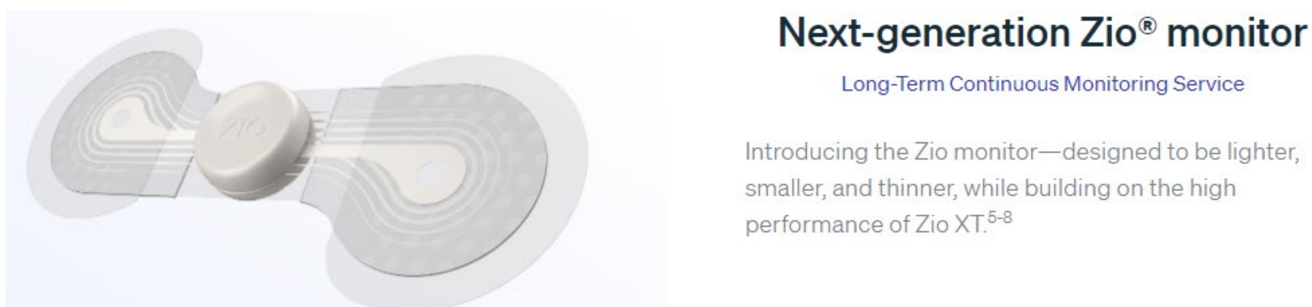
Claim 1	Accused Instrumentalities
	The Zio Monitor, our newest model, is 72% smaller and 62% lighter relative to the previous generation. The Zio Monitor uses 1 coin-cell battery, as compared to the 2 used in Zio XT. This is the second-most environmentally impactful component of our devices (after the circuit board). While we recycle these batteries, this is still a meaningful reduction in impact. (https://s201.q4cdn.com/653785554/files/doc_downloads/V4_-_iRhythm_ESG_Report_2023.pdf) **ZIO MONITOR SYSTEM** The Zio Monitor System is the next generation of the Zio XT System, and is a prescription-only, remote ECG monitoring system that consists of the Zio Monitor patch that records the electric signal from the heart continuously for up to 14 days and the ZEUS System, which supports the capture and analysis of ECG data recorded by the Zio Monitor patch at the end of the wear period, including specific arrhythmia events detected by the ZEUS algorithm. (https://s201.q4cdn.com/653785554/files/doc_downloads/V4_-_iRhythm_ESG_Report_2023.pdf)

Claim 1	**Accused Instrumentalities**
	

(Zio Monitor Teardown)

(Zio Monitor Teardown)

Claim 1	**Accused Instrumentalities**
	 (Zio Monitor Teardown)  (Zio Monitor Teardown)

Claim 1	**Accused Instrumentalities**
1[n] wherein the sealed housing includes rounded edges on a top surface,	***The Accused Instrumentalities includes wherein the sealed housing includes rounded edges on a top surface.*** The Zio Monitor satisfies 1[n] because the Zio Monitor includes a sealed housing with rounded edges on its top surface.  Zio Monitor (https://s201.q4cdn.com/653785554/files/doc_downloads/V4_-_iRhythm_ESG_Report_2023.pdf)  (https://www.irhythmtech.com/providers/zio-service/zio-monitors)

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Claim 1	Accused Instrumentalities
	• **Other features that make it easy to wear and allow patients to go about their daily lives**[8] – it is breathable, has a hydrocolloid adhesive and a waterproof housing[9,10], and requires no device or adhesive manipulation or battery change during the entire wear and monitoring period of up to 14 days. (https://www.globenewswire.com/news-release/2023/09/26/2749471/0/en/iRhythm-Launches-Next-Generation-Zio-Monitor-and-Enhanced-Zio-Service-Its-Smallest-Lightest-and-Thinnest-Cardiac-Monitor.html)  (Zio Monitor Teardown)

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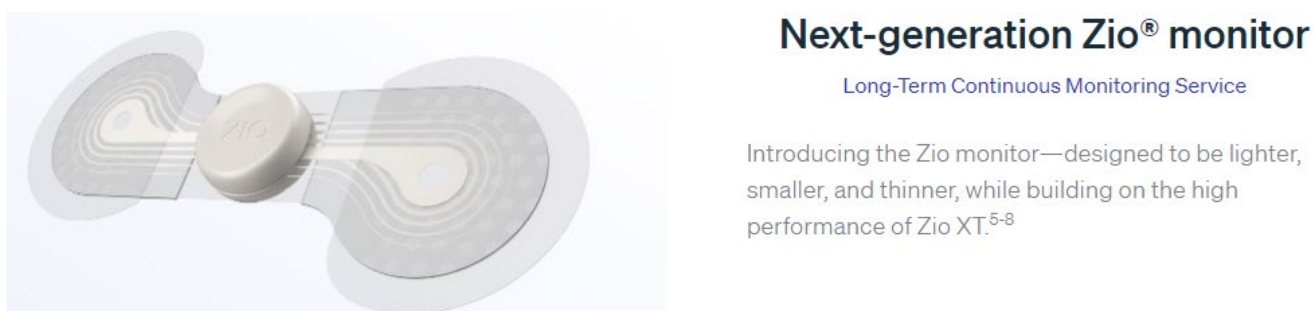
Claim 1	**Accused Instrumentalities**
	 (Zio Monitor Teardown)

<u>Claim 1</u>	<u>Accused Instrumentalities</u>
1[o] wherein the sealed housing is coupled to the flexible backing, and	***The Accused Instrumentalities include a sealed housing wherein the sealed housing is coupled to the flexible backing.*** The Zio Monitor satisfies 1[o] because the Zio Monitor includes a sealed housing that is coupled to the flexible backing.  Zio Monitor (https://s201.q4cdn.com/653785554/files/doc_downloads/V4_-_iRhythm_ESG_Report_2023.pdf)  (https://www.irhythmtech.com/providers/zio-service/zio-monitors)

<table>
<tr><th><u>Claim 1</u></th><th><u>Accused Instrumentalities</u></th></tr>
<tr><td></td><td>

(Zio Monitor Teardown)


(Zio Monitor Teardown)</td></tr>
</table>

Claim 1	Accused Instrumentalities
1[p] wherein the sealed housing includes a processor,	***The Accused Instrumentalities include a sealed housing wherein the sealed housing includes a processor.*** The Zio Monitor satisfies 1[p] because the Zio Monitor has a processer in its sealed housing. Day: From a technical viewpoint what we did was really to leverage a lot of advances not just in microprocessor efficiency, which is certainly part of it in terms of miniaturization as well as energy efficiency, but also we really challenged ourselves to figure out how to effectively fit in the smallest possible form factor, which for us was motivated a lot by the size of our battery, which is just a standard, easily available, and fortunately easily recyclable coin cell battery. We challenged ourselves to figure out how to miniaturize the device down to the level of one of those coin cells instead of the two that the Zio XT device uses. And that became feasible by the advances in microelectronic microprocessor efficiency and size as well through its miniaturization. But it also required a lot of really complicated dynamics from an electrical engineering perspective to figure out how to get all the components of a wearable medical device and a biosensor onto that small form factor. So, (https://www.mddionline.com/cardiovascular/behind-the-design-how-irhythm-built-its-new-zio-monitor)

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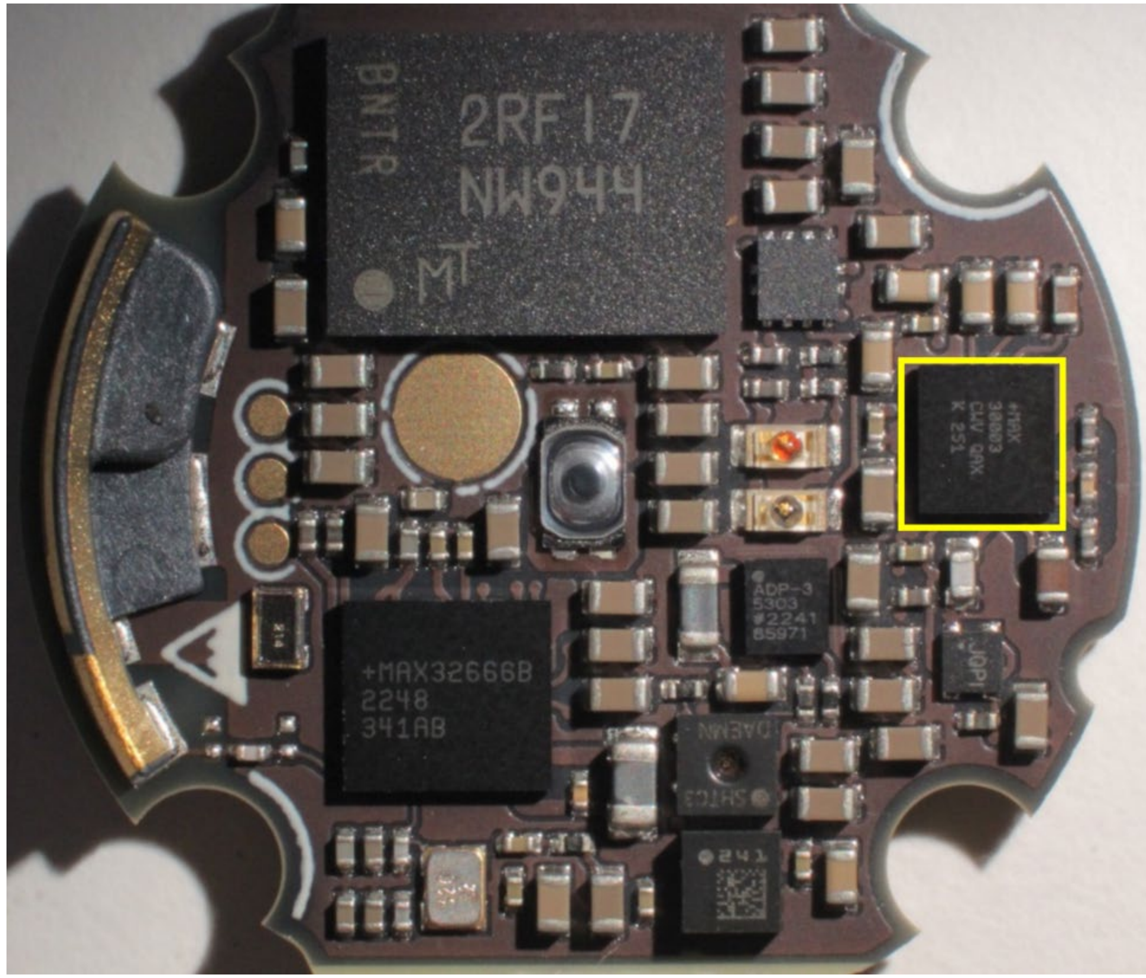
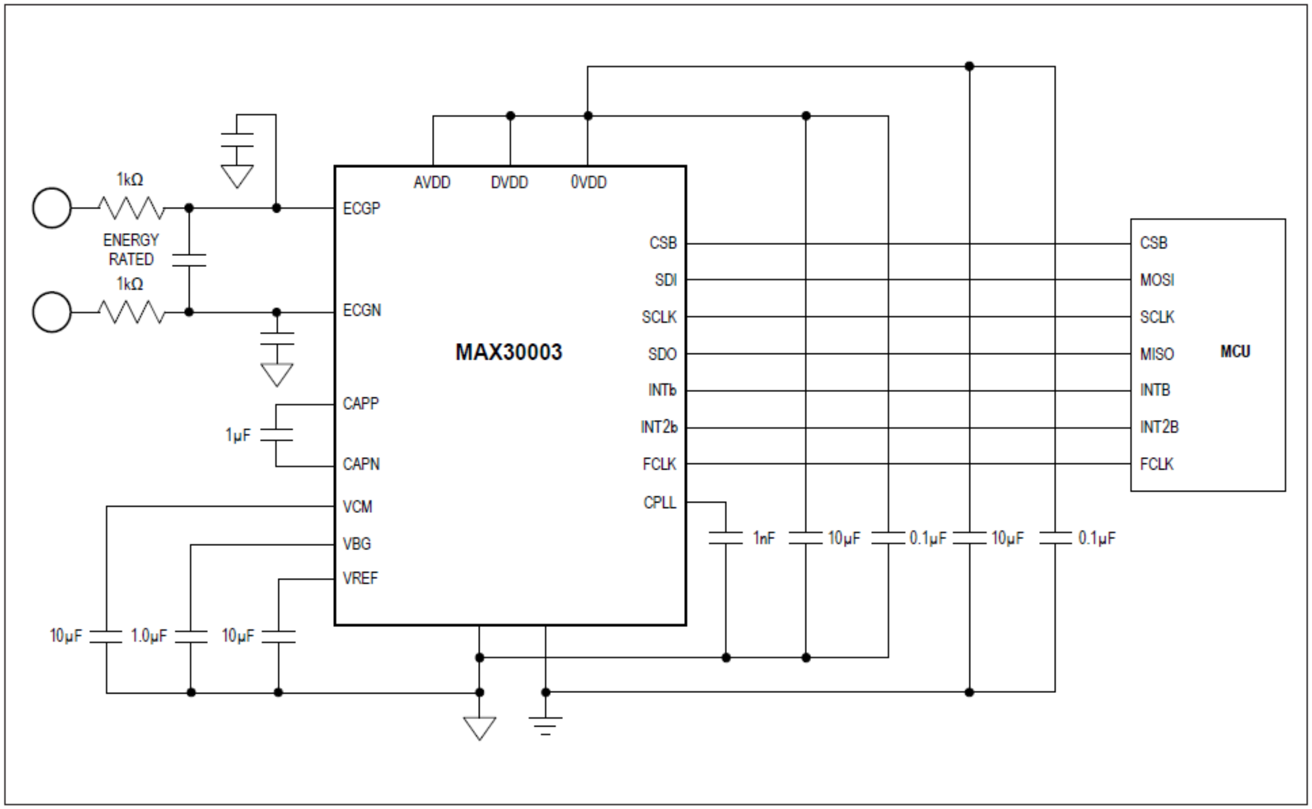
Claim 1	Accused Instrumentalities
	 (Zio Monitor Teardown)  (Zio Monitor Teardown)

Claim 1	Accused Instrumentalities
	 (Zio Monitor Teardown)  (Zio Monitor Teardown)

Claim 1	Accused Instrumentalities
	 (Zio Monitor Teardown)

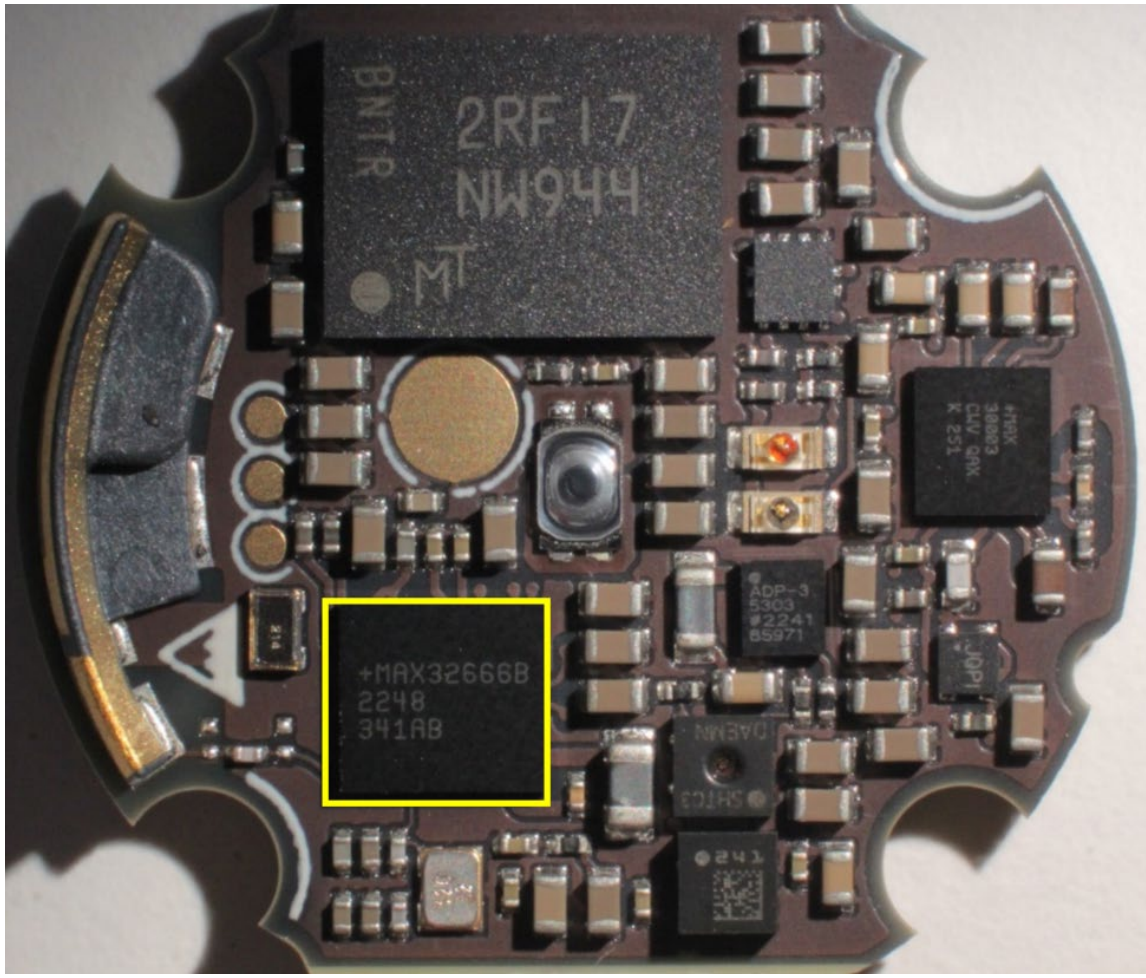
Claim 1	Accused Instrumentalities
	 (MAX30003 Datasheet)

Claim 1	Accused Instrumentalities
	ANALOG DEVICES Evaluation Kit Available · Design Resources · Tools and Models · Support *Click here to ask an associate for production status of specific part numbers.* **Ultra-Low Power, Single-Channel Integrated Biopotential (ECG, R-to-R Detection) AFE** **MAX30003** **General Description** The MAX30003 is a complete, biopotential, analog front-end solution for wearable applications. It offers high performance for clinical and fitness applications, with ultra-low power for long battery life. The MAX30003 is a single biopotential channel providing ECG waveforms and heart rate detection. The biopotential channel has ESD protection, EMI filtering, internal lead biasing, DC leads-off detection, ultra-low power leads-on detection during standby mode, and extensive calibration voltages for built-in self-test. Soft power-up sequencing ensures no large transients are injected into the electrodes. The biopotential channel also has high input impedance, low noise, high CMRR, programmable gain, various low-pass and high-pass filter options, and a high resolution analog-to-digital converter. The biopotential channel is DC coupled, can handle large electrode voltage offsets, and has a fast recovery mode to quickly recover from overdrive conditions, such as defibrillation and electrosurgery. The MAX30003 is available in a 28-pin TQFN and 30-bump wafer-level package (WLP), operating over the 0°C to +70°C commercial temperature range. (MAX30003 Datasheet)

Claim 1	Accused Instrumentalities

	Benefits and Features
	• Clinical-Grade ECG AFE with High-Resolution Data Converter
	  • 15.5 Bits Effective Resolution with 5μV_{P-P} Noise
	• Better Dry Starts Due to Much Improved Real World CMRR and High Input Impedance
	  • Fully Differential Input Structure with CMRR > 100dB
	• Offers Better Common-Mode to Differential Mode Conversion Due to High Input Impedance
	  • High Input Impedance > 500MΩ for Extremely Low Common-to-Differential Mode Conversion
	• Minimum Signal Attenuation at the Input During Dry Start Due to High Electrode Impedance
	• High DC Offset Range of ±650mV (1.8V, typ) Allows to Be Used with Wide Variety of Electrodes
	• High AC Dynamic Range of 65mV_{P-P} Will Help the AFE Not Saturate in the Presence of Motion/Direct Electrode Hits
	• Longer Battery Life Compared to Competing Solutions
	  • 85μW at 1.1V Supply Voltage
	• Leads-On Interrupt Feature Allows to Keep μC in Deep Sleep Mode with RTC Off Until Valid Lead Condition is Detected
	  • Lead-On Detect Current: 0.7μA (typ)
	
	(MAX30003 Datasheet)

Claim 1	Accused Instrumentalities
	• Built-In Heart Rate Detection with Interrupt Feature Eliminates the Need to Run HR Algorithm on the µController • Robust R-R Detection in High Motion Environment at Extremely Low Power • Configurable Interrupts Allows the µC Wake-Up Only on Every Heart Beat Reducing the Overall System Power • High Accuracy Allows for More Physiological Data Extractions • 32-Word FIFO Allows You to Wake Up µController Every 256ms with Full ECG Acquisition • High-Speed SPI Interface • Shutdown Current of 0.5µA (typ) (MAX30003 Datasheet) **R-to-R Detection** The MAX30003 contains built-in hardware to detect R-R intervals using an adaptation of the Pan-Tompkins QRS detection algorithm[1]. The timing resolution of the R-R interval is approximately 8ms and depends on the setting of FMSTR [1:0] in CNFG_GEN (0x10) register. See Table 22 for the timing resolution of each setting. (MAX30003 Datasheet)

Claim 1	**Accused Instrumentalities**
	 (Zio Monitor Teardown)

Claim 1	Accused Instrumentalities
	ANALOG DEVICES Click here to ask an associate for production status of specific part numbers. MAX32665/MAX32666 Low-Power Arm Cortex-M4 with FPU-Based Microcontroller with Bluetooth 5 for Wearables **General Description** DARWIN is a new breed of low-power microcontrollers built to thrive in the rapidly evolving Internet of Things (IoT). They are smart, with the biggest memories in their class and a massively scalable memory architecture. They run forever, thanks to wearable-grade power technology. They are durable enough to withstand the most advanced cyberattacks. DARWIN microcontrollers are designed to run any application imaginable—in places where you would not dream of sending other microcontrollers. Generation UB microcontrollers are designed to handle the increasingly complex applications demanded by today's advanced battery-powered devices and wirelessly connected devices, while providing robust hardware security and Bluetooth® 5 Low Energy (Bluetooth LE) radio connectivity. The MAX32665/MAX32666 UB class microcontrollers are advanced systems-on-chips featuring an Arm® Cortex®-M4 with FPU CPU for efficient computation of complex functions and algorithms with integrated power management. It also includes the newest generation Bluetooth 5 LE radio with support for long range (4x) and high throughput (2Mbps) and ADI's best-in-class hardware security suite trust protection unit (TPU). The devices offer large on-board memory with 1MB flash and 560KB SRAM. Split flash banks of 512KB each support seamless over-the-air upgrades, adding an additional degree of reliability. Memory scalability of data (SRAM) and code (Flash) space is supported by two SPI execute-in-place (SPIX) interfaces. (MAX32666 Datasheet)

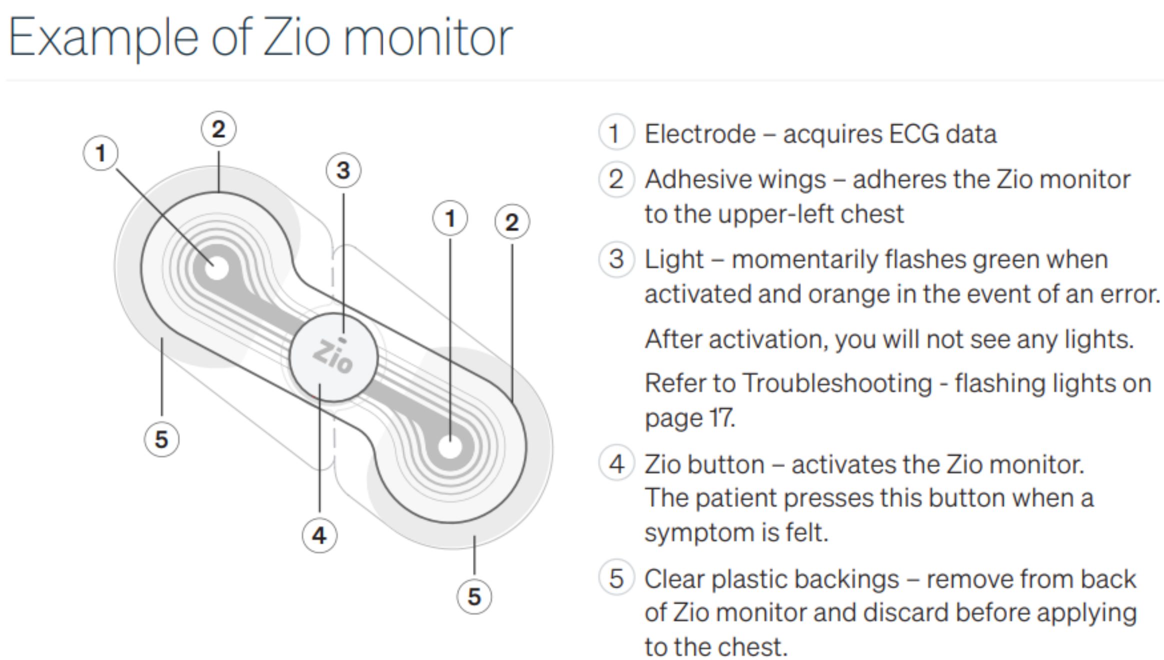
Claim 1	Accused Instrumentalities

	Multiple high-speed interfaces are supported including HS-USB, secure digital interface (SD, SDIO, MMC, SD-HC, and microSD™), SPI, UART, and I^2C serial interfaces, and an audio subsystem supporting PDM, PCM, I^2S, and TDM interfaces. An 8-input, 10-bit ADC is available to monitor analog inputs from external sensors and meters. The devices are available in 109-bump WLP (0.35mm pitch) and 121-bump CTBGA (0.65mm pitch).
	
	Applications
	• Connected Home
	• Industrial Sensors
	• Payment/Fitness/Medical Wearables
	• Telemedicine
	• Gaming Devices
	• Hearables
	
	(MAX32666 Datasheet)
	
	Benefits and Features
	• High-Efficiency Microcontroller and Audio DSP for Wearable and Hearable Devices
	  • Arm Cortex-M4 with FPU Up to 96MHz
	  • Optional Second Arm Cortex-M4 with FPU Optimized for Data Processing
	  • Low-Power, 7.3728MHz System Clock Option
	  • 1MB Flash, Organized into Dual Banks 2 x 512KB
	  • 560KB SRAM; 3 x 16KB Cache
	• Bluetooth 5 Low Energy Radio
	  • 1Mbps and 2Mbps Data Throughput
	  • Long Range (125kbps and 500kbps)
	  • Advertising Extension
	  • Rx Sensitivity: -95dbm; Tx Power Up to +4.5dbm
	  • On-Chip Matching with Single-Ended Antenna Port
	
	(MAX32666 Datasheet)

Claim 1	Accused Instrumentalities
	MAX32665/MAX32666 The MAX32665/MAX32666 are Arm Cortex-M4 with FPU-based microcontrollers with 1MB flash and 560KB SRAM. They are ideal for wearable medical fitness applications. A second Arm Cortex-M4 with FPU supporting ROM and cache supports extended data processing capabilities such as audio processing for wireless Bluetooth applications. The architecture includes a Bluetooth 5 Low Energy radio. The devices feature five powerful and flexible power modes. The flash memory is split into two banks of 512KB to provide flexibility when programming over the air. A built-in single inductor multiple output (SIMO) switch mode power supply allows the device to be optionally self-powered by a primary lithium cell. Dedicated hardware runs the Bluetooth 5 Low Energy stack freeing the CPUs for data processing tasks. Built-in dynamic clock gating and firmware-controlled power gating allow the user to optimize power for the specific application. Multiple SPI, UART, and I^2C serial interfaces, 1-Wire Master, and USB 2.0 High-Speed Device interface allow interconnection to a wide variety of external sensors. An audio subsystem supports PDM, PCM, I^2S, and TDM. An 8-input, 10-bit ADC is available to monitor analog input from external sensors and meters. The MAX32666 incorporates a trust protection unit (TPU) with encryption and advanced security features. These features include a modular arithmetic accelerator (MAA) for fast ECDSA, a hardware AES engine, a hardware TRNG entropy generator, a SHA-2 accelerator, and a secure bootloader. All devices are available in a 109-bump WLP with 0.35mm pitch and a 121-bump CTBGA with 0.65mm pitch packages. (MAX32666 Datasheet) **Arm Cortex-M4 with FPU Processor** The Arm Cortex-M4 with FPU processors CPU0 and CPU1 are ideal for the emerging category of wearable medical and wellness applications. The architecture combines high-efficiency signal processing functionality with low power, low cost, and ease of use. The Arm Cortex-M4 with FPU DSP supports single instruction multiple data (SIMD) path DSP extensions, providing: • Four parallel 8-bit add/sub • Floating point single precision • Two parallel 16-bit add/sub • Two parallel MACs • 32- or 64-bit accumulate • Signed, unsigned, data with or without saturation (MAX32666 Datasheet)

<table>
<tr><th><u>Claim 1</u></th><th><u>Accused Instrumentalities</u></th></tr>
<tr><td>1[q] wherein the processor is electrically coupled to the first electrocardiographic electrode, the second electrocardiographic electrode, and the battery,</td><td>

The Accused Instrumentalities include a processor wherein the processor is electrically coupled to the first electrocardiographic electrode, the second electrocardiographic electrode, and the battery. The Zio Monitor satisfies 1[q] because the Zio Monitor includes a processor that is electrically coupled to the electrodes and the battery.



(https://go.irhythmtech.com/hubfs/LB10117.01%20-%20ZIO%20MONITOR%20INSTRUCTIONS%20FOR%20USE%2c%20PRINTED%20(2).pdf)

</td></tr>
</table>

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Claim 1	Accused Instrumentalities
	Day: From a technical viewpoint what we did was really to leverage a lot of advances not just in microprocessor efficiency, which is certainly part of it in terms of miniaturization as well as energy efficiency, but also we really challenged ourselves to figure out how to effectively fit in the smallest possible form factor, which for us was motivated a lot by the size of our battery, which is just a standard, easily available, and fortunately easily recyclable coin cell battery. We challenged ourselves to figure out how to miniaturize the device down to the level of one of those coin cells instead of the two that the Zio XT device uses. And that became feasible by the advances in microelectronic microprocessor efficiency and size as well through its miniaturization. But it also required a lot of really complicated dynamics from an electrical engineering perspective to figure out how to get all the components of a wearable medical device and a biosensor onto that small form factor. So, miniaturization was focused on very clever ways of handling some of the larger components, which for example involved moving some of the big resistors that are required on the device to the more flexible part of the patch instead of on the actual printed circuit board in the housing. And this is a patented feature that we've already received a patent on it and we're pursuing more around it, but it was the idea that these three big resistors are not too big in terms of the homage that they have but also in terms of the size that they are. So, if you put them on the circuit board, they are these pretty big components, so we realized pretty early on that we couldn't really do that and still fit the design constraints. So, we innovated a different way, which was to integrate it into the ECG tracings themselves. (https://www.mddionline.com/cardiovascular/behind-the-design-how-irhythm-built-its-new-zio-monitor)

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Claim 1	Accused Instrumentalities
	The Zio Monitor, our newest model, is 72% smaller and 62% lighter relative to the previous generation. The Zio Monitor uses 1 coin-cell battery, as compared to the 2 used in Zio XT. This is the second-most environmentally impactful component of our devices (after the circuit board). While we recycle these batteries, this is still a meaningful reduction in impact. (https://s201.q4cdn.com/653785554/files/doc_downloads/V4_-_iRhythm_ESG_Report_2023.pdf) **ZIO MONITOR SYSTEM** The Zio Monitor System is the next generation of the Zio XT System, and is a prescription-only, remote ECG monitoring system that consists of the Zio Monitor patch that records the electric signal from the heart continuously for up to 14 days and the ZEUS System, which supports the capture and analysis of ECG data recorded by the Zio Monitor patch at the end of the wear period, including specific arrhythmia events detected by the ZEUS algorithm. (https://s201.q4cdn.com/653785554/files/doc_downloads/V4_-_iRhythm_ESG_Report_2023.pdf)

<table>
<tr><th><u>Claim 1</u></th><th><u>Accused Instrumentalities</u></th></tr>
<tr><td></td><td>

(Zio Monitor Teardown)

(Zio Monitor Teardown)</td></tr>
</table>

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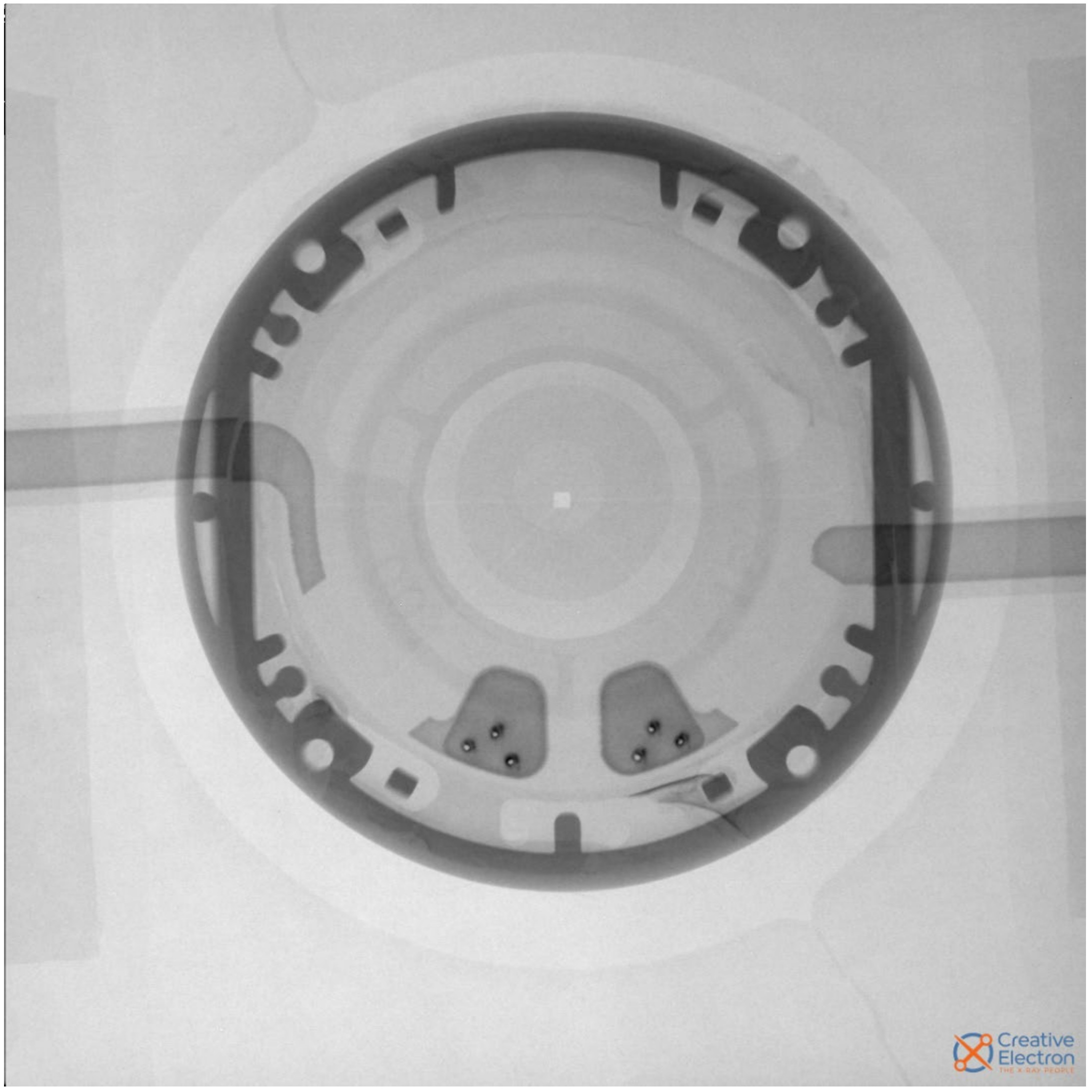
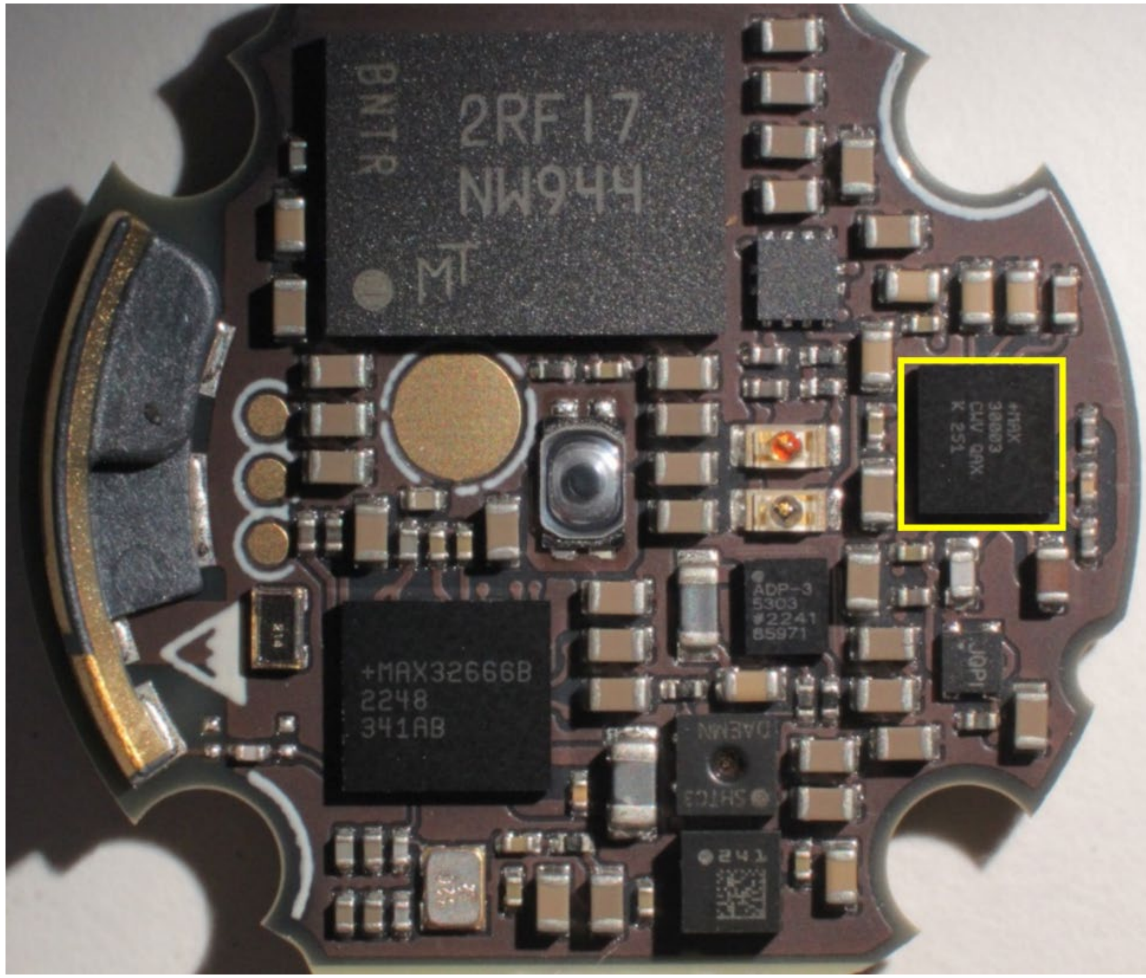
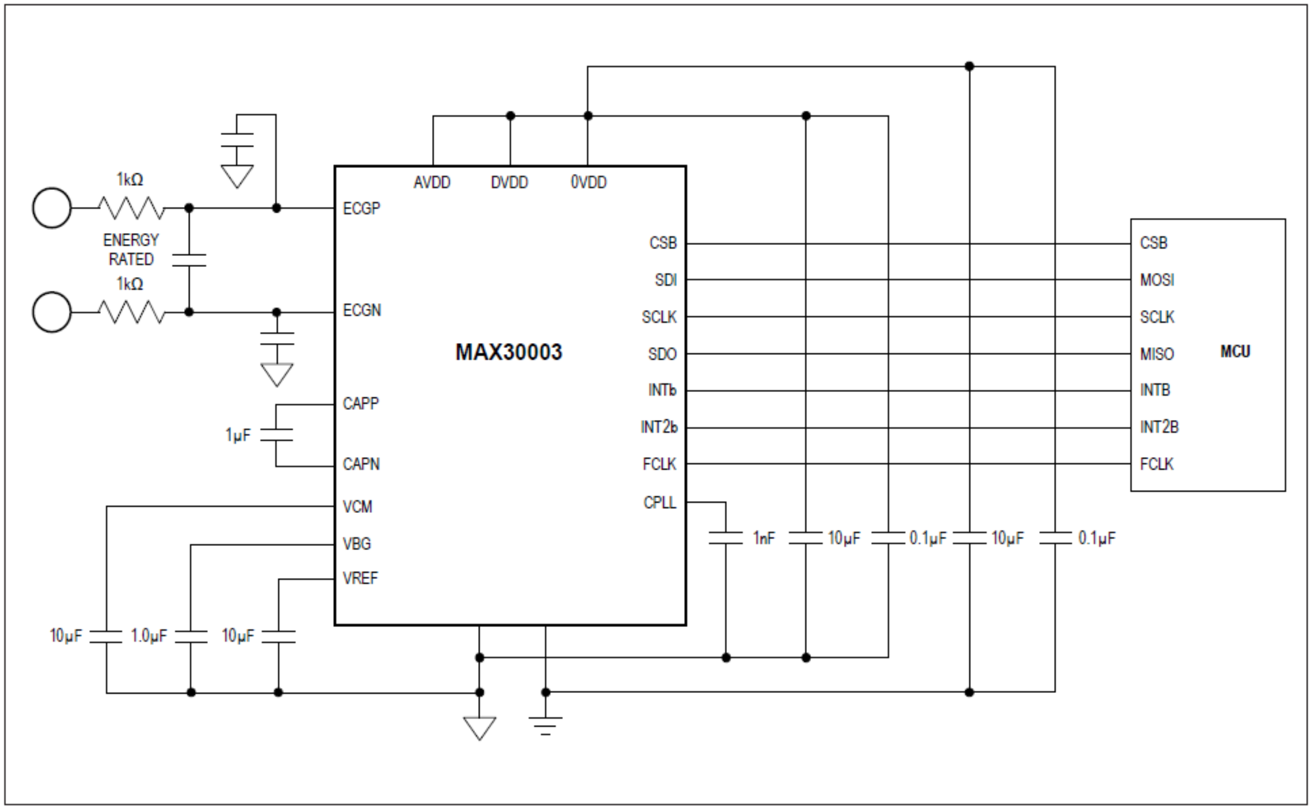
Claim 1	Accused Instrumentalities
	 (Zio Monitor Teardown)

Claim 1	Accused Instrumentalities
	 (Zio Monitor Teardown)

Claim 1	Accused Instrumentalities
	 (Zio Monitor Teardown)  (Zio Monitor Teardown)

<u>Claim 1</u>	**<u>Accused Instrumentalities</u>**
	 (Zio Monitor Teardown)

Claim 1	Accused Instrumentalities
	 (MAX30003 Datasheet)

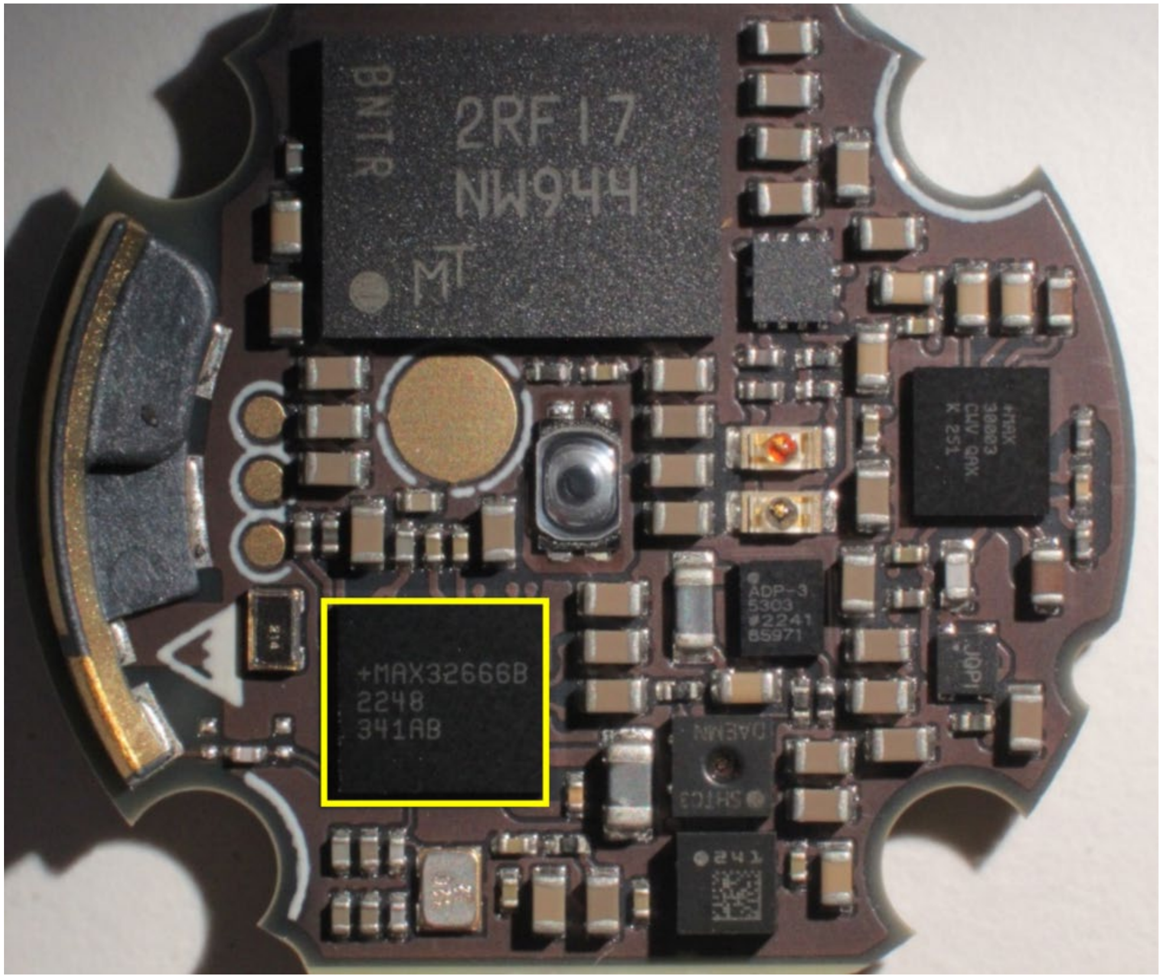
321652514.2

Claim 1	Accused Instrumentalities
	ANALOG DEVICES Evaluation Kit Available · Design Resources · Tools and Models · Support *Click here to ask an associate for production status of specific part numbers.* **Ultra-Low Power, Single-Channel Integrated Biopotential (ECG, R-to-R Detection) AFE** **MAX30003** **General Description** The MAX30003 is a complete, biopotential, analog front-end solution for wearable applications. It offers high performance for clinical and fitness applications, with ultra-low power for long battery life. The MAX30003 is a single biopotential channel providing ECG waveforms and heart rate detection. The biopotential channel has ESD protection, EMI filtering, internal lead biasing, DC leads-off detection, ultra-low power leads-on detection during standby mode, and extensive calibration voltages for built-in self-test. Soft power-up sequencing ensures no large transients are injected into the electrodes. The biopotential channel also has high input impedance, low noise, high CMRR, programmable gain, various low-pass and high-pass filter options, and a high resolution analog-to-digital converter. The biopotential channel is DC coupled, can handle large electrode voltage offsets, and has a fast recovery mode to quickly recover from overdrive conditions, such as defibrillation and electrosurgery. The MAX30003 is available in a 28-pin TQFN and 30-bump wafer-level package (WLP), operating over the 0°C to +70°C commercial temperature range. (MAX30003 Datasheet)

Claim 1	Accused Instrumentalities

	Benefits and Features
	• Clinical-Grade ECG AFE with High-Resolution Data Converter
	  • 15.5 Bits Effective Resolution with $5\mu V_{P-P}$ Noise
	• Better Dry Starts Due to Much Improved Real World CMRR and High Input Impedance
	  • Fully Differential Input Structure with CMRR > 100dB
	• Offers Better Common-Mode to Differential Mode Conversion Due to High Input Impedance
	  • High Input Impedance > 500MΩ for Extremely Low Common-to-Differential Mode Conversion
	• Minimum Signal Attenuation at the Input During Dry Start Due to High Electrode Impedance
	• High DC Offset Range of ±650mV (1.8V, typ) Allows to Be Used with Wide Variety of Electrodes
	• High AC Dynamic Range of $65mV_{P-P}$ Will Help the AFE Not Saturate in the Presence of Motion/Direct Electrode Hits
	• Longer Battery Life Compared to Competing Solutions
	  • 85μW at 1.1V Supply Voltage
	• Leads-On Interrupt Feature Allows to Keep μC in Deep Sleep Mode with RTC Off Until Valid Lead Condition is Detected
	  • Lead-On Detect Current: 0.7μA (typ)
	
	(MAX30003 Datasheet)

Claim 1	Accused Instrumentalities
	• Built-In Heart Rate Detection with Interrupt Feature Eliminates the Need to Run HR Algorithm on the µController • Robust R-R Detection in High Motion Environment at Extremely Low Power • Configurable Interrupts Allows the µC Wake-Up Only on Every Heart Beat Reducing the Overall System Power • High Accuracy Allows for More Physiological Data Extractions • 32-Word FIFO Allows You to Wake Up µController Every 256ms with Full ECG Acquisition • High-Speed SPI Interface • Shutdown Current of 0.5µA (typ) (MAX30003 Datasheet) **R-to-R Detection** The MAX30003 contains built-in hardware to detect R-R intervals using an adaptation of the Pan-Tompkins QRS detection algorithm[1]. The timing resolution of the R-R interval is approximately 8ms and depends on the setting of FMSTR [1:0] in CNFG_GEN (0x10) register. See Table 22 for the timing resolution of each setting. (MAX30003 Datasheet)

Claim 1	Accused Instrumentalities
	 (Zio Monitor Teardown)

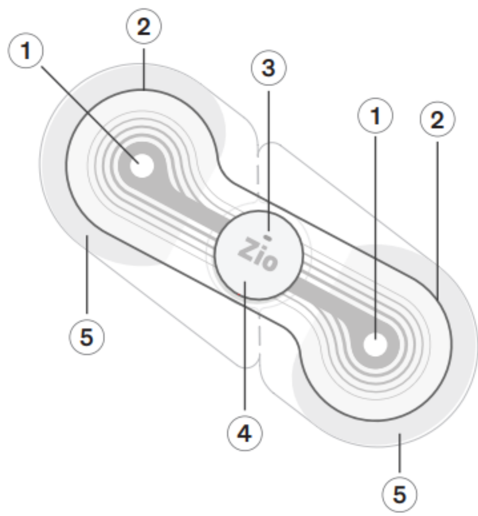
Claim 1	Accused Instrumentalities
	ANALOG DEVICES Click here to ask an associate for production status of specific part numbers. MAX32665/MAX32666 Low-Power Arm Cortex-M4 with FPU-Based Microcontroller with Bluetooth 5 for Wearables **General Description** DARWIN is a new breed of low-power microcontrollers built to thrive in the rapidly evolving Internet of Things (IoT). They are smart, with the biggest memories in their class and a massively scalable memory architecture. They run forever, thanks to wearable-grade power technology. They are durable enough to withstand the most advanced cyberattacks. DARWIN microcontrollers are designed to run any application imaginable—in places where you would not dream of sending other microcontrollers. Generation UB microcontrollers are designed to handle the increasingly complex applications demanded by today's advanced battery-powered devices and wirelessly connected devices, while providing robust hardware security and Bluetooth® 5 Low Energy (Bluetooth LE) radio connectivity. The MAX32665/MAX32666 UB class microcontrollers are advanced systems-on-chips featuring an Arm® Cortex®-M4 with FPU CPU for efficient computation of complex functions and algorithms with integrated power management. It also includes the newest generation Bluetooth 5 LE radio with support for long range (4x) and high throughput (2Mbps) and ADI's best-in-class hardware security suite trust protection unit (TPU). The devices offer large on-board memory with 1MB flash and 560KB SRAM. Split flash banks of 512KB each support seamless over-the-air upgrades, adding an additional degree of reliability. Memory scalability of data (SRAM) and code (Flash) space is supported by two SPI execute-in-place (SPIX) interfaces. (MAX32666 Datasheet)

Claim 1	Accused Instrumentalities

	Multiple high-speed interfaces are supported including HS-USB, secure digital interface (SD, SDIO, MMC, SD-HC, and microSD™), SPI, UART, and I^2C serial interfaces, and an audio subsystem supporting PDM, PCM, I^2S, and TDM interfaces. An 8-input, 10-bit ADC is available to monitor analog inputs from external sensors and meters. The devices are available in 109-bump WLP (0.35mm pitch) and 121-bump CTBGA (0.65mm pitch).
	
	Applications
	• Connected Home
	• Industrial Sensors
	• Payment/Fitness/Medical Wearables
	• Telemedicine
	• Gaming Devices
	• Hearables
	
	(MAX32666 Datasheet)
	
	Benefits and Features
	• High-Efficiency Microcontroller and Audio DSP for Wearable and Hearable Devices
	  • Arm Cortex-M4 with FPU Up to 96MHz
	  • Optional Second Arm Cortex-M4 with FPU Optimized for Data Processing
	  • Low-Power, 7.3728MHz System Clock Option
	  • 1MB Flash, Organized into Dual Banks 2 x 512KB
	  • 560KB SRAM; 3 x 16KB Cache
	• Bluetooth 5 Low Energy Radio
	  • 1Mbps and 2Mbps Data Throughput
	  • Long Range (125kbps and 500kbps)
	  • Advertising Extension
	  • Rx Sensitivity: -95dbm; Tx Power Up to +4.5dbm
	  • On-Chip Matching with Single-Ended Antenna Port
	
	(MAX32666 Datasheet)

Claim 1	**Accused Instrumentalities**
	MAX32665/MAX32666 The MAX32665/MAX32666 are Arm Cortex-M4 with FPU-based microcontrollers with 1MB flash and 560KB SRAM. They are ideal for wearable medical fitness applications. A second Arm Cortex-M4 with FPU supporting ROM and cache supports extended data processing capabilities such as audio processing for wireless Bluetooth applications. The architecture includes a Bluetooth 5 Low Energy radio. The devices feature five powerful and flexible power modes. The flash memory is split into two banks of 512KB to provide flexibility when programming over the air. A built-in single inductor multiple output (SIMO) switch mode power supply allows the device to be optionally self-powered by a primary lithium cell. Dedicated hardware runs the Bluetooth 5 Low Energy stack freeing the CPUs for data processing tasks. Built-in dynamic clock gating and firmware-controlled power gating allow the user to optimize power for the specific application. Multiple SPI, UART, and I^2C serial interfaces, 1-Wire Master, and USB 2.0 High-Speed Device interface allow interconnection to a wide variety of external sensors. An audio subsystem supports PDM, PCM, I^2S, and TDM. An 8-input, 10-bit ADC is available to monitor analog input from external sensors and meters. The MAX32666 incorporates a trust protection unit (TPU) with encryption and advanced security features. These features include a modular arithmetic accelerator (MAA) for fast ECDSA, a hardware AES engine, a hardware TRNG entropy generator, a SHA-2 accelerator, and a secure bootloader. All devices are available in a 109-bump WLP with 0.35mm pitch and a 121-bump CTBGA with 0.65mm pitch packages. (MAX32666 Datasheet) **Arm Cortex-M4 with FPU Processor** The Arm Cortex-M4 with FPU processors CPU0 and CPU1 are ideal for the emerging category of wearable medical and wellness applications. The architecture combines high-efficiency signal processing functionality with low power, low cost, and ease of use. The Arm Cortex-M4 with FPU DSP supports single instruction multiple data (SIMD) path DSP extensions, providing: ● Four parallel 8-bit add/sub ● Floating point single precision ● Two parallel 16-bit add/sub ● Two parallel MACs ● 32- or 64-bit accumulate ● Signed, unsigned, data with or without saturation (MAX32666 Datasheet)

<u>**Claim 1**</u>	<u>**Accused Instrumentalities**</u>
1[r] wherein the processor is configured to process the electrocardiographic signals sensed via the first electrocardiographic electrode and the second electrocardiographic electrode; and	***The Accused Instrumentalities include a processor wherein the processor is configured to process the electrocardiographic signals sensed via the first electrocardiographic electrode and the second electrocardiographic electrode.*** The Zio Monitor satisfies 1[r] because the Zio Monitor processes electrocardiographic signals sensed by its electrocardiographic electrodes. **Product Description** The Zio® ECG Monitoring System is an ambulatory Electrocardiogram (ECG) monitoring system. The Zio ECG Monitoring System consists of two components: (1) Zio monitor (2) proprietary algorithm software. The Zio monitor is a single-use ECG monitor that provides a continuous, single-channel recording for up to 14 days. The Zio monitor records ECG data without patient interaction, with the goal of improving patient compliance via simplicity of operation. Patients have the option of pressing a convenient button and filling out a log to document symptomatic events, which will support symptom-rhythm correlation in the diagnostic report. After conclusion of the wear period (up to 14 days), the patient removes the Zio monitor and returns it by mail to iRhythm for processing. After receipt, the data is analyzed by iRhythm's proprietary algorithm before a Certified Cardiographic Technician (CCT) reviews the results and generates a report of the key findings. (https://go.irhythmtech.com/hubfs/LB10117.01%20-%20ZIO%20MONITOR%20INSTRUCTIONS%20FOR%20USE%2c%20PRINTED%20(2).pdf)

Claim 1	**Accused Instrumentalities**
	Example of Zio monitor  1 Electrode – acquires ECG data 2 Adhesive wings – adheres the Zio monitor to the upper-left chest 3 Light – momentarily flashes green when activated and orange in the event of an error. After activation, you will not see any lights. Refer to Troubleshooting - flashing lights on page 17. 4 Zio button – activates the Zio monitor. The patient presses this button when a symptom is felt. 5 Clear plastic backings – remove from back of Zio monitor and discard before applying to the chest. https://go.irhythmtech.com/hubfs/LB10117.01%20-%20ZIO%20MONITOR%20INSTRUCTIONS%20FOR%20USE%2c%20PRINTED%20(2).pdf

Claim 1	Accused Instrumentalities
	ZIO MONITOR SYSTEM The Zio Monitor System is the next generation of the Zio XT System, and is a prescription-only, remote ECG monitoring system that consists of the Zio Monitor patch that records the electric signal from the heart continuously for up to 14 days and the ZEUS System, which supports the capture and analysis of ECG data recorded by the Zio Monitor patch at the end of the wear period, including specific arrhythmia events detected by the ZEUS algorithm. (https://s201.q4cdn.com/653785554/files/doc_downloads/V4_-_iRhythm_ESG_Report_2023.pdf) Zio Monitor Zio XT Zio AT Long-term continuous monitoring service The new Zio monitor is designed with patients in mind by providing a more breathable, inconspicuous, and comfortable wear experience so patients can go about their daily activities.[5,15,16] (https://www.irhythmtech.com/providers/zio-service/zio-monitors)

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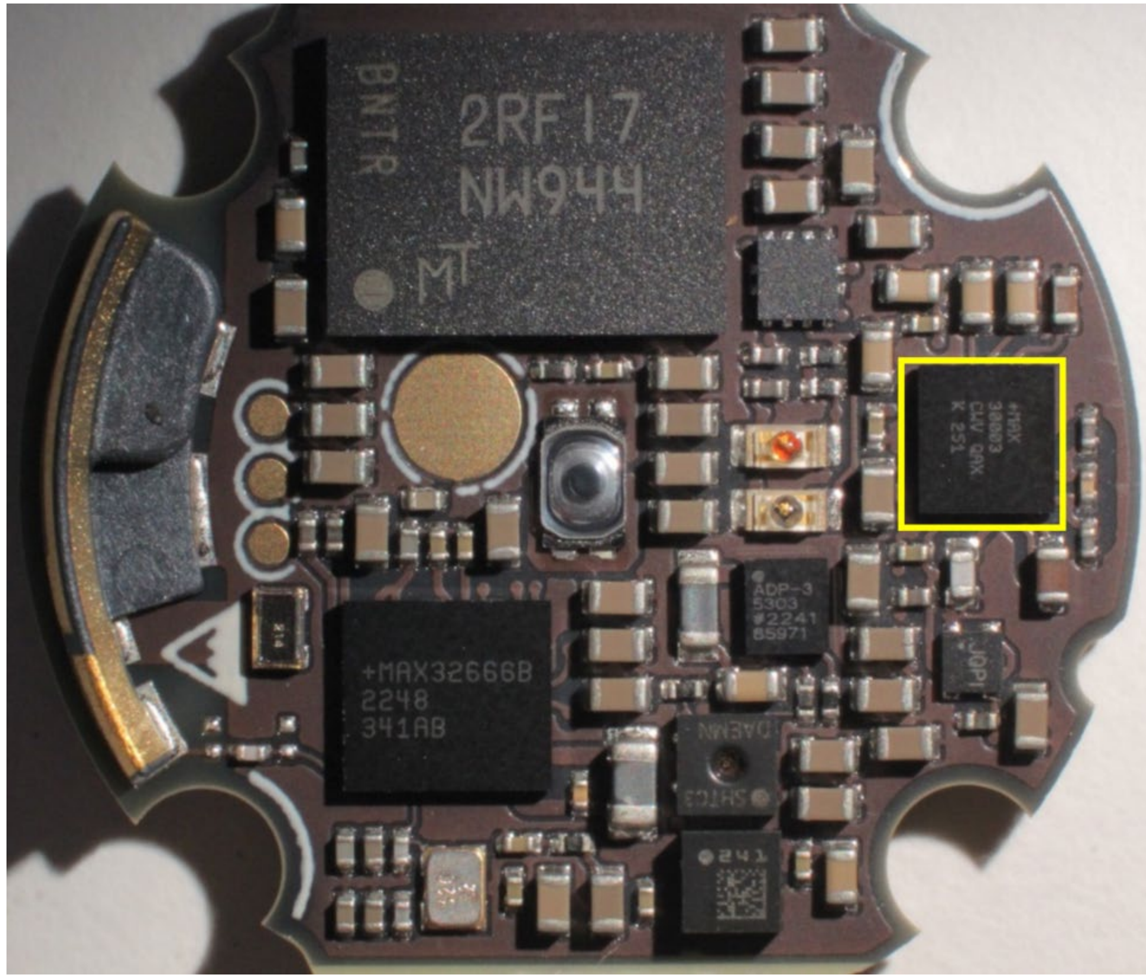
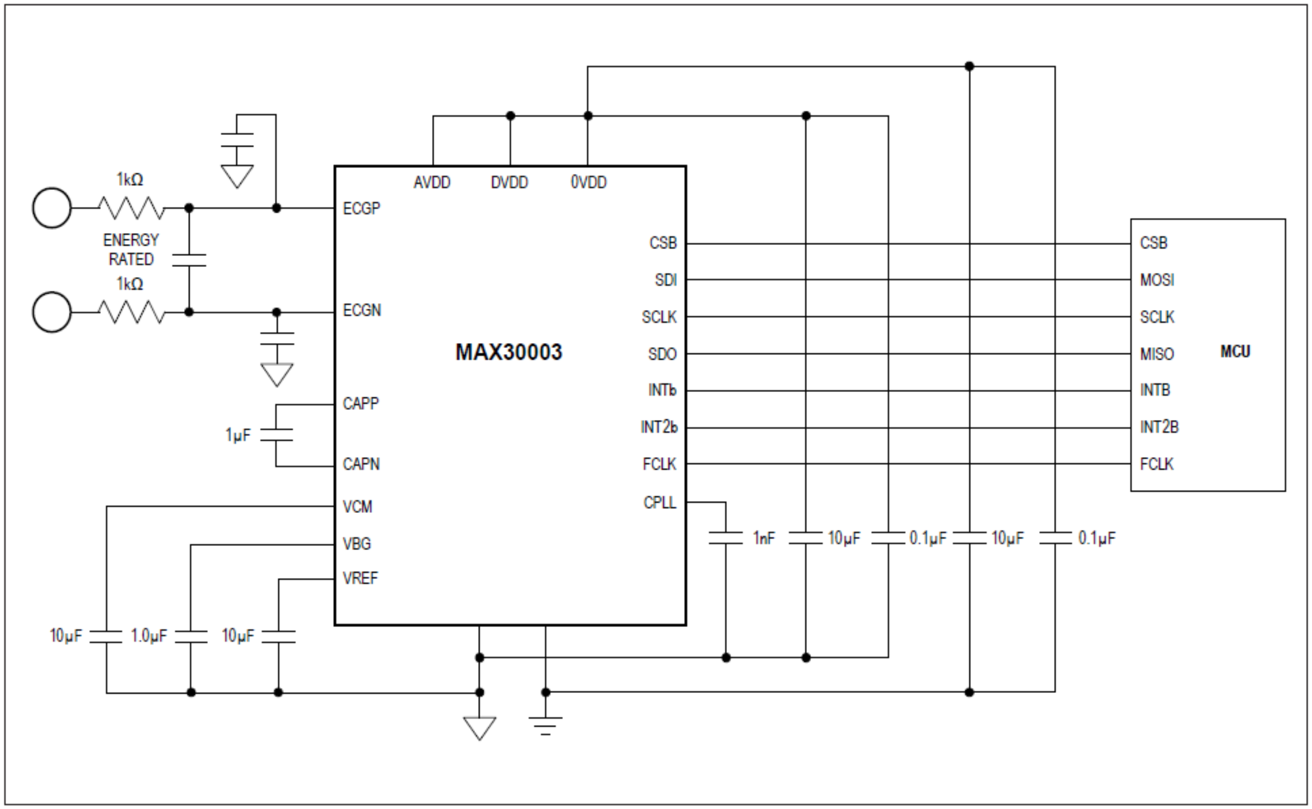
Claim 1	Accused Instrumentalities
	 (Zio Monitor Teardown)  (Zio Monitor Teardown)

Claim 1	Accused Instrumentalities
	 (Zio Monitor Teardown)  (Zio Monitor Teardown)

Claim 1	**Accused Instrumentalities**
	 (Zio Monitor Teardown)

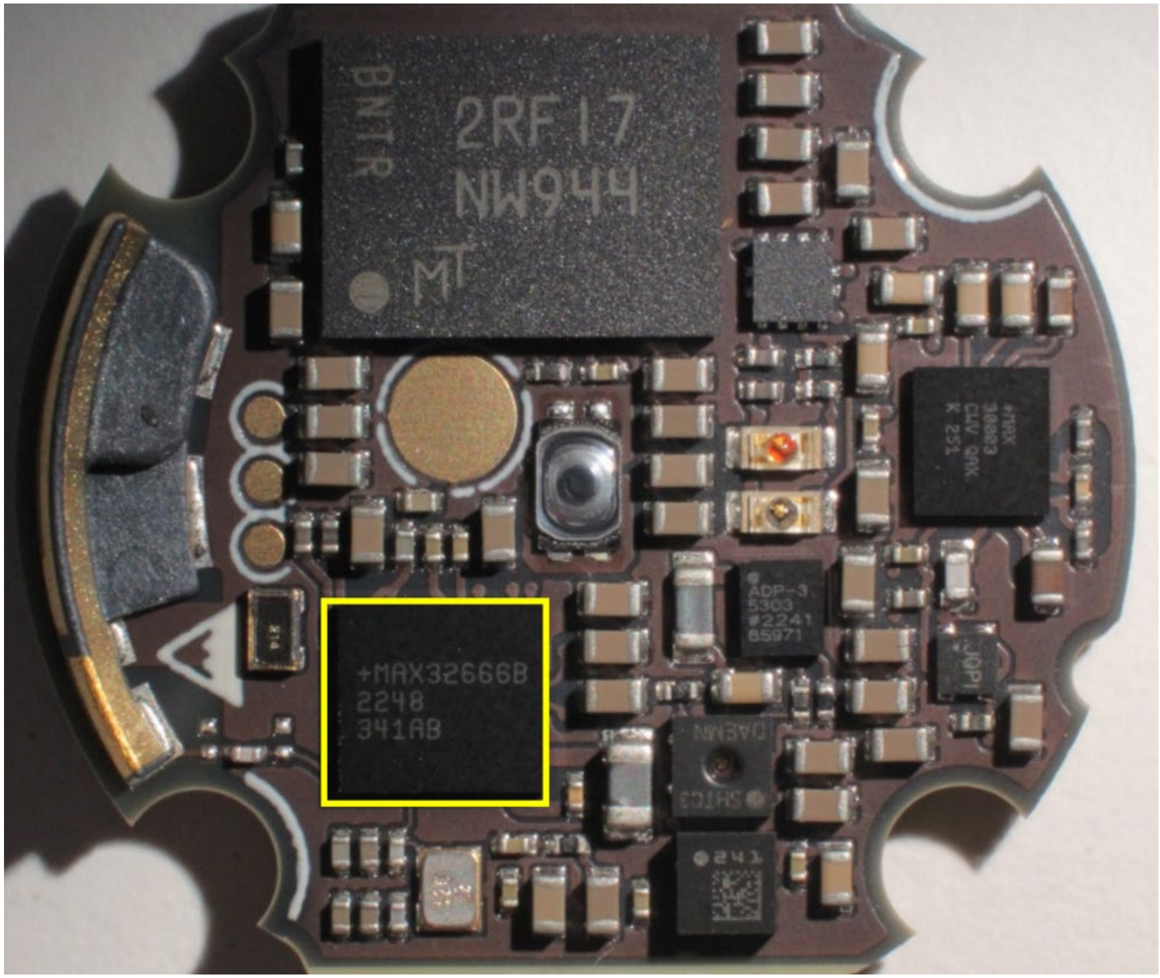
Claim 1	Accused Instrumentalities
	 (MAX30003 Datasheet)

Claim 1	Accused Instrumentalities
	ANALOG DEVICES Evaluation Kit Available · Design Resources · Tools and Models · Support *Click here to ask an associate for production status of specific part numbers.* **Ultra-Low Power, Single-Channel Integrated Biopotential (ECG, R-to-R Detection) AFE** **MAX30003** **General Description** The MAX30003 is a complete, biopotential, analog front-end solution for wearable applications. It offers high performance for clinical and fitness applications, with ultra-low power for long battery life. The MAX30003 is a single biopotential channel providing ECG waveforms and heart rate detection. The biopotential channel has ESD protection, EMI filtering, internal lead biasing, DC leads-off detection, ultra-low power leads-on detection during standby mode, and extensive calibration voltages for built-in self-test. Soft power-up sequencing ensures no large transients are injected into the electrodes. The biopotential channel also has high input impedance, low noise, high CMRR, programmable gain, various low-pass and high-pass filter options, and a high resolution analog-to-digital converter. The biopotential channel is DC coupled, can handle large electrode voltage offsets, and has a fast recovery mode to quickly recover from overdrive conditions, such as defibrillation and electrosurgery. The MAX30003 is available in a 28-pin TQFN and 30-bump wafer-level package (WLP), operating over the 0°C to +70°C commercial temperature range. (MAX30003 Datasheet)

Claim 1	Accused Instrumentalities

	Benefits and Features
	• Clinical-Grade ECG AFE with High-Resolution Data Converter
	  • 15.5 Bits Effective Resolution with $5\mu V_{P-P}$ Noise
	• Better Dry Starts Due to Much Improved Real World CMRR and High Input Impedance
	  • Fully Differential Input Structure with CMRR > 100dB
	• Offers Better Common-Mode to Differential Mode Conversion Due to High Input Impedance
	  • High Input Impedance > 500MΩ for Extremely Low Common-to-Differential Mode Conversion
	• Minimum Signal Attenuation at the Input During Dry Start Due to High Electrode Impedance
	• High DC Offset Range of ±650mV (1.8V, typ) Allows to Be Used with Wide Variety of Electrodes
	• High AC Dynamic Range of $65mV_{P-P}$ Will Help the AFE Not Saturate in the Presence of Motion/Direct Electrode Hits
	• Longer Battery Life Compared to Competing Solutions
	  • 85µW at 1.1V Supply Voltage
	• Leads-On Interrupt Feature Allows to Keep µC in Deep Sleep Mode with RTC Off Until Valid Lead Condition is Detected
	  • Lead-On Detect Current: 0.7µA (typ)
	
	(MAX30003 Datasheet)

Claim 1	Accused Instrumentalities
	• Built-In Heart Rate Detection with Interrupt Feature Eliminates the Need to Run HR Algorithm on the µController ◦ Robust R-R Detection in High Motion Environment at Extremely Low Power • Configurable Interrupts Allows the µC Wake-Up Only on Every Heart Beat Reducing the Overall System Power • High Accuracy Allows for More Physiological Data Extractions • 32-Word FIFO Allows You to Wake Up µController Every 256ms with Full ECG Acquisition • High-Speed SPI Interface • Shutdown Current of 0.5µA (typ) (MAX30003 Datasheet) **R-to-R Detection** The MAX30003 contains built-in hardware to detect R-R intervals using an adaptation of the Pan-Tompkins QRS detection algorithm[1]. The timing resolution of the R-R interval is approximately 8ms and depends on the setting of FMSTR [1:0] in CNFG_GEN (0x10) register. See Table 22 for the timing resolution of each setting. (MAX30003 Datasheet)

Claim 1	**Accused Instrumentalities**
	 (Zio Monitor Teardown)

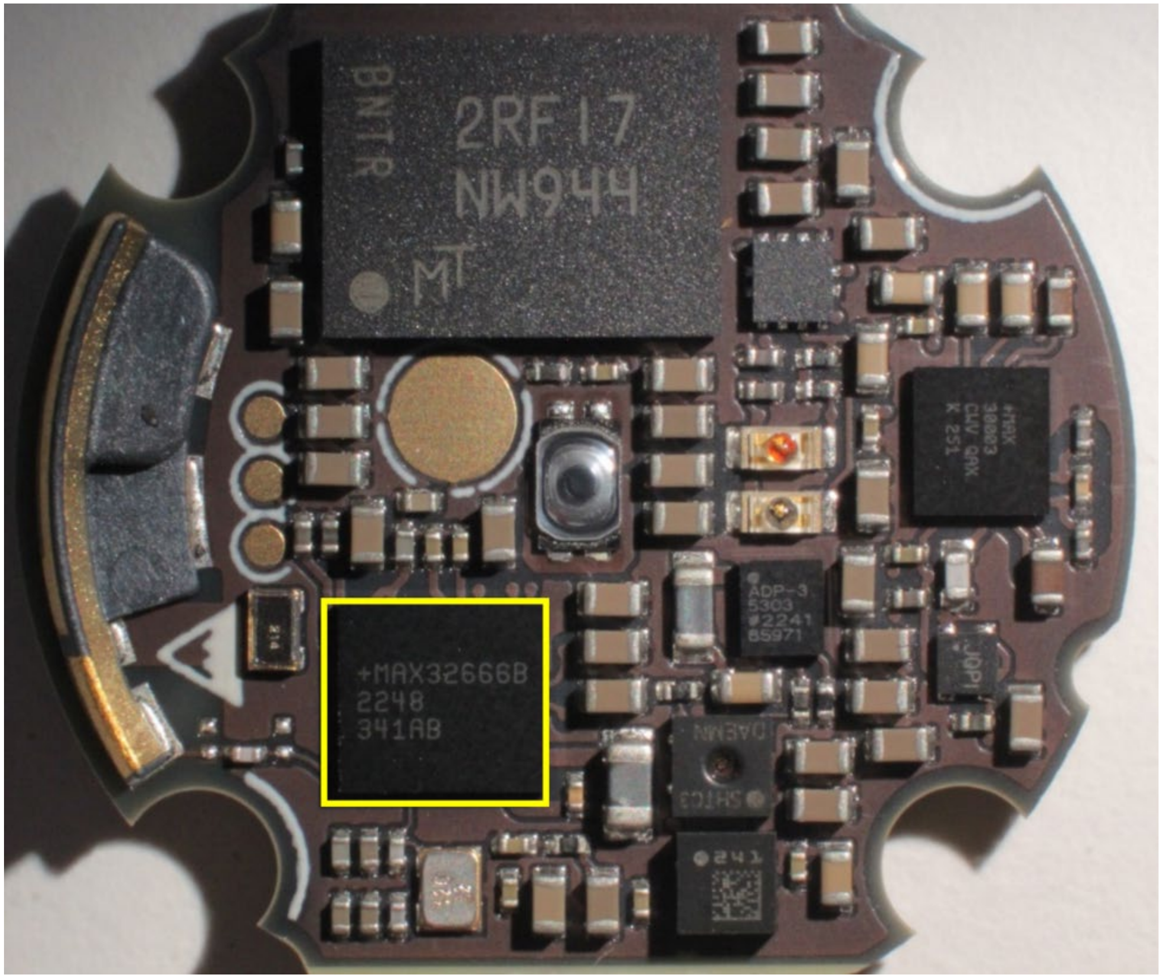
Claim 1	Accused Instrumentalities
	ANALOG DEVICES Click here to ask an associate for production status of specific part numbers. MAX32665/MAX32666 Low-Power Arm Cortex-M4 with FPU-Based Microcontroller with Bluetooth 5 for Wearables **General Description** DARWIN is a new breed of low-power microcontrollers built to thrive in the rapidly evolving Internet of Things (IoT). They are smart, with the biggest memories in their class and a massively scalable memory architecture. They run forever, thanks to wearable-grade power technology. They are durable enough to withstand the most advanced cyberattacks. DARWIN microcontrollers are designed to run any application imaginable—in places where you would not dream of sending other microcontrollers. Generation UB microcontrollers are designed to handle the increasingly complex applications demanded by today's advanced battery-powered devices and wirelessly connected devices, while providing robust hardware security and Bluetooth® 5 Low Energy (Bluetooth LE) radio connectivity. The MAX32665/MAX32666 UB class microcontrollers are advanced systems-on-chips featuring an Arm® Cortex®-M4 with FPU CPU for efficient computation of complex functions and algorithms with integrated power management. It also includes the newest generation Bluetooth 5 LE radio with support for long range (4x) and high throughput (2Mbps) and ADI's best-in-class hardware security suite trust protection unit (TPU). The devices offer large on-board memory with 1MB flash and 560KB SRAM. Split flash banks of 512KB each support seamless over-the-air upgrades, adding an additional degree of reliability. Memory scalability of data (SRAM) and code (Flash) space is supported by two SPI execute-in-place (SPIX) interfaces. (MAX32666 Datasheet)

Claim 1	Accused Instrumentalities

	Multiple high-speed interfaces are supported including HS-USB, secure digital interface (SD, SDIO, MMC, SD-HC, and microSD™), SPI, UART, and I^2C serial interfaces, and an audio subsystem supporting PDM, PCM, I^2S, and TDM interfaces. An 8-input, 10-bit ADC is available to monitor analog inputs from external sensors and meters. The devices are available in 109-bump WLP (0.35mm pitch) and 121-bump CTBGA (0.65mm pitch).
	
	Applications
	• Connected Home
	• Industrial Sensors
	• Payment/Fitness/Medical Wearables
	• Telemedicine
	• Gaming Devices
	• Hearables
	
	(MAX32666 Datasheet)
	
	Benefits and Features
	• High-Efficiency Microcontroller and Audio DSP for Wearable and Hearable Devices
	  • Arm Cortex-M4 with FPU Up to 96MHz
	  • Optional Second Arm Cortex-M4 with FPU Optimized for Data Processing
	  • Low-Power, 7.3728MHz System Clock Option
	  • 1MB Flash, Organized into Dual Banks 2 x 512KB
	  • 560KB SRAM; 3 x 16KB Cache
	• Bluetooth 5 Low Energy Radio
	  • 1Mbps and 2Mbps Data Throughput
	  • Long Range (125kbps and 500kbps)
	  • Advertising Extension
	  • Rx Sensitivity: -95dbm; Tx Power Up to +4.5dbm
	  • On-Chip Matching with Single-Ended Antenna Port
	
	(MAX32666 Datasheet)

Claim 1	Accused Instrumentalities
	MAX32665/MAX32666 The MAX32665/MAX32666 are Arm Cortex-M4 with FPU-based microcontrollers with 1MB flash and 560KB SRAM. They are ideal for wearable medical fitness applications. A second Arm Cortex-M4 with FPU supporting ROM and cache supports extended data processing capabilities such as audio processing for wireless Bluetooth applications. The architecture includes a Bluetooth 5 Low Energy radio. The devices feature five powerful and flexible power modes. The flash memory is split into two banks of 512KB to provide flexibility when programming over the air. A built-in single inductor multiple output (SIMO) switch mode power supply allows the device to be optionally self-powered by a primary lithium cell. Dedicated hardware runs the Bluetooth 5 Low Energy stack freeing the CPUs for data processing tasks. Built-in dynamic clock gating and firmware-controlled power gating allow the user to optimize power for the specific application. Multiple SPI, UART, and I^2C serial interfaces, 1-Wire Master, and USB 2.0 High-Speed Device interface allow interconnection to a wide variety of external sensors. An audio subsystem supports PDM, PCM, I^2S, and TDM. An 8-input, 10-bit ADC is available to monitor analog input from external sensors and meters. The MAX32666 incorporates a trust protection unit (TPU) with encryption and advanced security features. These features include a modular arithmetic accelerator (MAA) for fast ECDSA, a hardware AES engine, a hardware TRNG entropy generator, a SHA-2 accelerator, and a secure bootloader. All devices are available in a 109-bump WLP with 0.35mm pitch and a 121-bump CTBGA with 0.65mm pitch packages. (MAX32666 Datasheet) **Arm Cortex-M4 with FPU Processor** The Arm Cortex-M4 with FPU processors CPU0 and CPU1 are ideal for the emerging category of wearable medical and wellness applications. The architecture combines high-efficiency signal processing functionality with low power, low cost, and ease of use. The Arm Cortex-M4 with FPU DSP supports single instruction multiple data (SIMD) path DSP extensions, providing: • Four parallel 8-bit add/sub • Floating point single precision • Two parallel 16-bit add/sub • Two parallel MACs • 32- or 64-bit accumulate • Signed, unsigned, data with or without saturation (MAX32666 Datasheet)

Claim 1	**Accused Instrumentalities**
1[s] a wireless transceiver, wherein the wireless transceiver draws power from the battery.	***The Accused Instrumentalities include a wireless transceiver.*** The Zio Monitor satisfies 1[s] because the Zio Monitor includes a wireless transceiver and a battery. The wireless transceiver draws power from the battery.  (Zio Monitor Teardown)

Claim 1	Accused Instrumentalities
	 (Zio Monitor Teardown)

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	Applications
	• Connected Home
	• Industrial Sensors
	• Payment/Fitness/Medical Wearables
	• Telemedicine
	• Gaming Devices
	• Hearables
	(MAX32666 Datasheet)
	Benefits and Features
	• High-Efficiency Microcontroller and Audio DSP for Wearable and Hearable Devices
	  • Arm Cortex-M4 with FPU Up to 96MHz
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	  • Low-Power, 7.3728MHz System Clock Option
	  • 1MB Flash, Organized into Dual Banks 2 x 512KB
	  • 560KB SRAM; 3 x 16KB Cache
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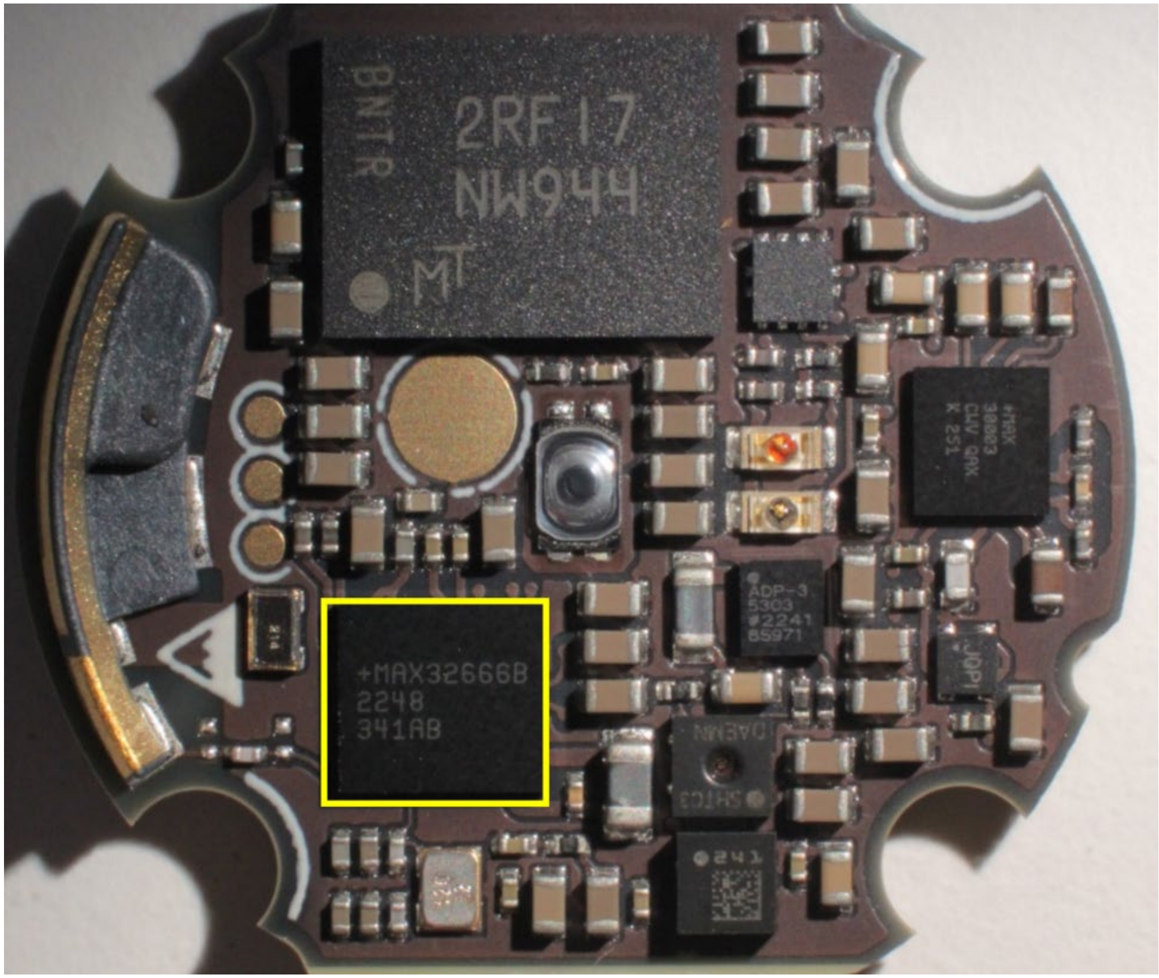
	  • Long Range (125kbps and 500kbps)
	  • Advertising Extension
	  • Rx Sensitivity: -95dbm; Tx Power Up to +4.5dbm
	  • On-Chip Matching with Single-Ended Antenna Port
	(MAX32666 Datasheet)

Claim 1	Accused Instrumentalities
	MAX32665/MAX32666 The MAX32665/MAX32666 are Arm Cortex-M4 with FPU-based microcontrollers with 1MB flash and 560KB SRAM. They are ideal for wearable medical fitness applications. A second Arm Cortex-M4 with FPU supporting ROM and cache supports extended data processing capabilities such as audio processing for wireless Bluetooth applications. The architecture includes a Bluetooth 5 Low Energy radio. The devices feature five powerful and flexible power modes. The flash memory is split into two banks of 512KB to provide flexibility when programming over the air. A built-in single inductor multiple output (SIMO) switch mode power supply allows the device to be optionally self-powered by a primary lithium cell. Dedicated hardware runs the Bluetooth 5 Low Energy stack freeing the CPUs for data processing tasks. Built-in dynamic clock gating and firmware-controlled power gating allow the user to optimize power for the specific application. Multiple SPI, UART, and I^2C serial interfaces, 1-Wire Master, and USB 2.0 High-Speed Device interface allow interconnection to a wide variety of external sensors. An audio subsystem supports PDM, PCM, I^2S, and TDM. An 8-input, 10-bit ADC is available to monitor analog input from external sensors and meters. The MAX32666 incorporates a trust protection unit (TPU) with encryption and advanced security features. These features include a modular arithmetic accelerator (MAA) for fast ECDSA, a hardware AES engine, a hardware TRNG entropy generator, a SHA-2 accelerator, and a secure bootloader. All devices are available in a 109-bump WLP with 0.35mm pitch and a 121-bump CTBGA with 0.65mm pitch packages. (MAX32666 Datasheet) **Arm Cortex-M4 with FPU Processor** The Arm Cortex-M4 with FPU processors CPU0 and CPU1 are ideal for the emerging category of wearable medical and wellness applications. The architecture combines high-efficiency signal processing functionality with low power, low cost, and ease of use. The Arm Cortex-M4 with FPU DSP supports single instruction multiple data (SIMD) path DSP extensions, providing: • Four parallel 8-bit add/sub • Floating point single precision • Two parallel 16-bit add/sub • Two parallel MACs • 32- or 64-bit accumulate • Signed, unsigned, data with or without saturation (MAX32666 Datasheet)

<u>**Claim 2**</u>	<u>**Accused Instrumentalities**</u>
2. The wearable electrocardiography monitoring device of Claim 1, wherein the mid-section comprises a first edge parallel to a second edge.	***The Accused Instrumentalities include the wearable electrocardiography monitoring device of Claim 1, wherein the mid-section comprises a first edge parallel to a second edge.*** The Zio Monitor satisfies Claim 2 because the Zio Monitor includes a mid-section that is narrower than each end section. *See, e.g.*, 1[c]; *see also* 8[d]. The mid-section has two edges (i.e., a first edge and a second edge) that are parallel to each other. *See, e.g.*, 1[c]; *see also* 8[d].

Claim 3	**Accused Instrumentalities**
3. The wearable electrocardiography monitoring device of Claim 1, wherein the wireless transceiver is configured to communicate with an external device via Wi-Fi, mobile phone communication standards, or Bluetooth.	***The Accused Instrumentalities include the wearable electrocardiography monitoring device of Claim 1, wherein the wireless transceiver is configured to communicate with an external device via Wi-Fi, mobile phone communication standards, or Bluetooth.*** The Zio Monitor satisfies Claim 3 because the Zio Monitor includes a wireless transceiver that communicates with an external device, for example, via Bluetooth. *See, e.g.*, 1[s].  (Zio Monitor Teardown)

Claim 3	Accused Instrumentalities
	 (Zio Monitor Teardown)

Claim 3	Accused Instrumentalities
	ANALOG DEVICES Click here to ask an associate for production status of specific part numbers. MAX32665/MAX32666 Low-Power Arm Cortex-M4 with FPU-Based Microcontroller with Bluetooth 5 for Wearables **General Description** DARWIN is a new breed of low-power microcontrollers built to thrive in the rapidly evolving Internet of Things (IoT). They are smart, with the biggest memories in their class and a massively scalable memory architecture. They run forever, thanks to wearable-grade power technology. They are durable enough to withstand the most advanced cyberattacks. DARWIN microcontrollers are designed to run any application imaginable—in places where you would not dream of sending other microcontrollers. Generation UB microcontrollers are designed to handle the increasingly complex applications demanded by today's advanced battery-powered devices and wirelessly connected devices, while providing robust hardware security and Bluetooth® 5 Low Energy (Bluetooth LE) radio connectivity. The MAX32665/MAX32666 UB class microcontrollers are advanced systems-on-chips featuring an Arm® Cortex®-M4 with FPU CPU for efficient computation of complex functions and algorithms with integrated power management. It also includes the newest generation Bluetooth 5 LE radio with support for long range (4x) and high throughput (2Mbps) and ADI's best-in-class hardware security suite trust protection unit (TPU). The devices offer large on-board memory with 1MB flash and 560KB SRAM. Split flash banks of 512KB each support seamless over-the-air upgrades, adding an additional degree of reliability. Memory scalability of data (SRAM) and code (Flash) space is supported by two SPI execute-in-place (SPIX) interfaces. (MAX32666 Datasheet)

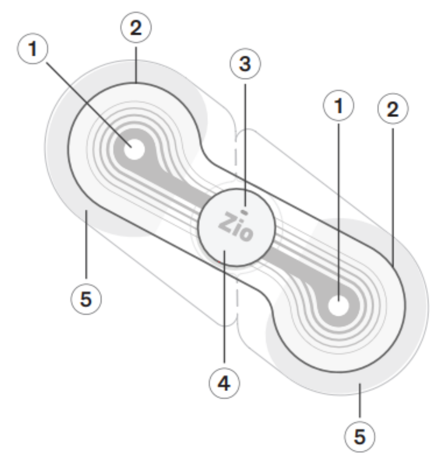
Claim 3	Accused Instrumentalities

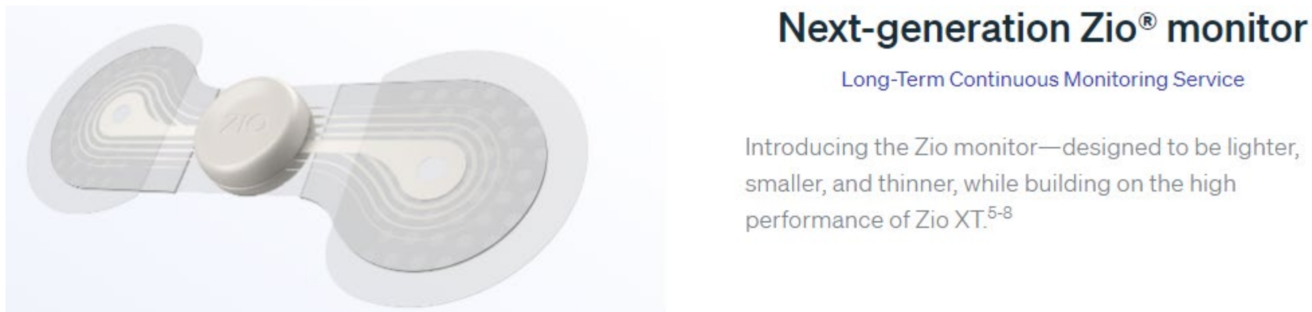
	Multiple high-speed interfaces are supported including HS-USB, secure digital interface (SD, SDIO, MMC, SD-HC, and microSD™), SPI, UART, and I^2C serial interfaces, and an audio subsystem supporting PDM, PCM, I^2S, and TDM interfaces. An 8-input, 10-bit ADC is available to monitor analog inputs from external sensors and meters. The devices are available in 109-bump WLP (0.35mm pitch) and 121-bump CTBGA (0.65mm pitch).
	
	Applications
	• Connected Home
	• Industrial Sensors
	• Payment/Fitness/Medical Wearables
	• Telemedicine
	• Gaming Devices
	• Hearables
	
	(MAX32666 Datasheet)
	
	Benefits and Features
	• High-Efficiency Microcontroller and Audio DSP for Wearable and Hearable Devices
	  • Arm Cortex-M4 with FPU Up to 96MHz
	  • Optional Second Arm Cortex-M4 with FPU Optimized for Data Processing
	  • Low-Power, 7.3728MHz System Clock Option
	  • 1MB Flash, Organized into Dual Banks 2 x 512KB
	  • 560KB SRAM; 3 x 16KB Cache
	• Bluetooth 5 Low Energy Radio
	  • 1Mbps and 2Mbps Data Throughput
	  • Long Range (125kbps and 500kbps)
	  • Advertising Extension
	  • Rx Sensitivity: -95dbm; Tx Power Up to +4.5dbm
	  • On-Chip Matching with Single-Ended Antenna Port
	
	(MAX32666 Datasheet)

Claim 3	Accused Instrumentalities
	MAX32665/MAX32666 The MAX32665/MAX32666 are Arm Cortex-M4 with FPU-based microcontrollers with 1MB flash and 560KB SRAM. They are ideal for wearable medical fitness applications. A second Arm Cortex-M4 with FPU supporting ROM and cache supports extended data processing capabilities such as audio processing for wireless Bluetooth applications. The architecture includes a Bluetooth 5 Low Energy radio. The devices feature five powerful and flexible power modes. The flash memory is split into two banks of 512KB to provide flexibility when programming over the air. A built-in single inductor multiple output (SIMO) switch mode power supply allows the device to be optionally self-powered by a primary lithium cell. Dedicated hardware runs the Bluetooth 5 Low Energy stack freeing the CPUs for data processing tasks. Built-in dynamic clock gating and firmware-controlled power gating allow the user to optimize power for the specific application. Multiple SPI, UART, and I^2C serial interfaces, 1-Wire Master, and USB 2.0 High-Speed Device interface allow interconnection to a wide variety of external sensors. An audio subsystem supports PDM, PCM, I^2S, and TDM. An 8-input, 10-bit ADC is available to monitor analog input from external sensors and meters. The MAX32666 incorporates a trust protection unit (TPU) with encryption and advanced security features. These features include a modular arithmetic accelerator (MAA) for fast ECDSA, a hardware AES engine, a hardware TRNG entropy generator, a SHA-2 accelerator, and a secure bootloader. All devices are available in a 109-bump WLP with 0.35mm pitch and a 121-bump CTBGA with 0.65mm pitch packages. (MAX32666 Datasheet) **Arm Cortex-M4 with FPU Processor** The Arm Cortex-M4 with FPU processors CPU0 and CPU1 are ideal for the emerging category of wearable medical and wellness applications. The architecture combines high-efficiency signal processing functionality with low power, low cost, and ease of use. The Arm Cortex-M4 with FPU DSP supports single instruction multiple data (SIMD) path DSP extensions, providing: • Four parallel 8-bit add/sub • Floating point single precision • Two parallel 16-bit add/sub • Two parallel MACs • 32- or 64-bit accumulate • Signed, unsigned, data with or without saturation (MAX32666 Datasheet)

Claim 6	**Accused Instrumentalities**
6. The wearable electrocardiography monitoring device of Claim 1, wherein the adhesive covering the portion of the first face of the strip is provided on the first end section and the second end section only.	***The Accused Instrumentalities include the wearable electrocardiography monitoring device of Claim 1, wherein the adhesive covering the portion of the first face of the strip is provided on the first end section and the second end section only.*** The Zio Monitor satisfies Claim 6 because the Zio Monitor includes an under side (i.e., a first face) and an upper side (i.e., a second face). *See* 1[b]. The Zio Monitor includes two wing portions that are covered in adhesive to adhere the strip to skin of a patient. *See id.* Further, the mid-section portion of the Zio Monitor is not covered in adhesive. *See id.*

Claim 8	**Accused Instrumentalities**
8[pre] A wearable electrocardiography monitoring device, comprising:	***To the extent the preamble is deemed to be a limitation, the Accused Instrumentalities include a wearable electrocardiography monitoring device in accordance with this claim.*** The Zio Monitor satisfies 8[pre] because the Zio Monitor is a device that is worn on the patient's body. *See* 1[pre].
8[a] a flexible backing including a strip comprising:	***The Accused Instrumentalities include a flexible backing including a strip.*** The Zio Monitor satisfies 8[a] because the Zio Monitor includes a flexible backing including a strip. *See* 1[a].
8[b] a first face and a second face, wherein a portion of the first face is covered in adhesive to adhere the strip to skin of a patient,	***The Accused Instrumentalities include a first face and a second face, wherein a portion of the first face is covered in adhesive to adhere the strip to skin of a patient.*** The Zio Monitor satisfies 8[b] because the Zio Monitor includes an under side (i.e., a first face) and an upper side (i.e., a second face). *See* 1[b]; 6. The Zio Monitor includes two wing portions that are covered in adhesive to adhere the strip to skin of a patient. *See* 1[b]; 6.
8[c] a first end section, a second end section opposite the first end	***The Accused Instrumentalities include a first end section, a second end section opposite the first end section, and a mid-section between the first end section and the second end section.*** The Zio Monitor satisfies 8[c] because the Zio Monitor includes a first end section that is opposite a second

Claim 8	Accused Instrumentalities
section, and a mid-section between the first end section and the second end section;	end section. *See* 1[c]. The Zio Monitor also includes a mid-section between the first end section and the second end section. *See id.*
8[d] wherein the mid-section is narrower than the first end section and the second end section, and wherein the mid-section comprises a first edge parallel to a second edge;	***The Accused Instrumentalities include a mid-section wherein the mid-section is narrower than the first end section and the second end section, and wherein the mid-section comprises a first edge parallel to a second edge.*** The Zio Monitor satisfies 8[d] because the Zio Monitor includes a mid-section that is narrower than each end section. *See* 1[c]. The mid-section has two edges (i.e., a first edge and a second edge) that are parallel to each other. *See, e.g.*, *id.* Example of Zio monitor  (https://go.irhythmtech.com/hubfs/LB10117.01%20-%20ZIO%20MONITOR%20INSTRUCTIONS%20FOR%20USE%2c%20PRINTED%20(2).pdf)

Claim 8	**Accused Instrumentalities**
	 (https://www.irhythmtech.com/providers/zio-service/zio-monitors)  (Zio Monitor Teardown)

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Claim 8	**Accused Instrumentalities**
8[e] a flexible circuit mounted to the second face of the strip, the flexible circuit comprising a first circuit trace and a second circuit trace;	***The Accused Instrumentalities include a flexible circuit mounted to the second face of the strip, the flexible circuit comprising a first circuit trace and a second circuit trace.*** The Zio Monitor satisfies 8[e] because the Zio Monitor includes a flexible circuit comprising two circuit traces (i.e., a first circuit trace and a second circuit trace). *See* 1[d]. The flexible circuit is mounted to the upper side of the strip (i.e., second face). *See id.*
8[f] a first electrocardiographic electrode and a second electrocardiographic electrode,	***The Accused Instrumentalities include a first electrocardiographic electrode and a second electrocardiographic electrode.*** The Zio Monitor satisfies 8[f] because the Zio Monitor includes two elecrocardiographic electrodes. *See* 1[e].
8[g] wherein the first electrocardiographic electrode and the second electrocardiographic electrode are configured to sense electrocardiographic signals,	***The Accused Instrumentalities include wherein the first electrocardiographic electrode and the second electrocardiographic electrode are configured to sense electrocardiographic signals.*** The Zio Monitor satisfies 8[g] because the Zio Monitor includes two electrocardiographic electrodes that sense electrocardiographic signals. *See* 1[f].
8[h] wherein the first electrocardiographic electrode and the second electrocardiographic electrode are coupled to the flexible circuit,	***The Accused Instrumentalities include wherein the first electrocardiographic electrode and the second electrocardiographic electrode are coupled to the flexible circuit.*** The Zio Monitor satisfies 8[h] because the Zio Monitor has electrocardiographic electrodes that are coupled to the flexible circuit. *See* 1[g].
8[i] wherein the first electrocardiographic electrode is conductively exposed at the first face	***The Accused Instrumentalities include wherein the first electrocardiographic electrode is conductively exposed at the first face along the first end section of the strip.*** The Zio Monitor satisfies 8[i] because the Zio Monitor includes an electrocardiographic electrode conductively exposed on the upper side (i.e., the first face) along one end (i.e., the first end section) of the strip. *See* 1[h].

<u>**Claim 8**</u>	<u>**Accused Instrumentalities**</u>
along the first end section of the strip,	
8[j] wherein the second electrocardiographic electrode is conductively exposed at the first face along the second end section of the strip,	***The Accused Instrumentalities include wherein the second electrocardiographic electrode is conductively exposed at the first face along the second end section of the strip.*** The Zio Monitor satisfies 8[j] because the Zio Monitor includes an electrocardiographic electrode conductively exposed on the upper side (i.e., the first face) along one end (i.e., the second end section) of the strip. *See* 1[i].
8[k] wherein the first circuit trace is electrically coupled to the first electrocardiographic electrode, and	***The Accused Instrumentalities include wherein the first circuit trace is electrically coupled to the first electrocardiographic electrode.*** The Zio Monitor satisfies 8[k] because the Zio Monitor includes circuit traces, one of which is electrically coupled to one of the electrocardiographic electrodes (i.e., the first electrocardiographic electrode). *See* 1[j].
8[l] wherein the second circuit trace is electrically coupled to the second electrocardiographic electrode;	***The Accused Instrumentalities include wherein the second circuit trace is electrically coupled to the second electrocardiographic electrode.*** The Zio Monitor satisfies 8[l] because the Zio Monitor includes circuit traces, one of which is coupled to one of the electrocardiographic electrodes (i.e., the second electrocardiographic electrode). *See* 1[k].
8[m] wherein the first electrocardiographic electrode includes an inline resistor;	***The Accused Instrumentalities include wherein the first electrocardiographic electrode includes an inline resistor.*** The Zio Monitor satisfies 8[m] because the Zio Monitor includes an inline resistor located on the flexible backing. Further, the inline resister is integrated into the ECG tracings. *See* 1[l].
8[n] a battery;	***The Accused Instrumentalities include a battery.*** The Zio Monitor satisfies 8[n] because the Zio Monitor includes a battery. *See* 1[m]. The battery powers the body worn device. *See id.*
8[o] a wireless transceiver, wherein the wireless transceiver draws power from the battery; and	***The Accused Instrumentalities include a wireless transceiver, wherein the wireless transceiver draws power from the battery.*** The Zio Monitor satisfies 8[o] because the Zio Monitor includes a wireless transceiver that draws power from the battery. *See* 1[s].

Claim 8	**Accused Instrumentalities**
8[p] a sealed housing having rounded edges on a top surface,	***The Accused Instrumentalities include a sealed housing having rounded edges on a top surface.*** The Zio Monitor satisfies 8[p] because the Zio Monitor includes a sealed housing with rounded edges on its top surface. *See* 1[n].
8[q] wherein the sealed housing is coupled to the flexible backing, and	***The Accused Instrumentalities include a sealed housing wherein the sealed housing is coupled to the flexible backing.*** The Zio Monitor satisfies 8[q] because the Zio Monitor includes a sealed housing that is coupled to the flexible backing. *See* 1[o].
8[r] wherein the sealed housing includes a processor,	***The Accused Instrumentalities include a sealed housing wherein the sealed housing includes a processor.*** The Zio Monitor satisfies 8[r] because the Zio Monitor has a processer in its sealed housing. *See* 1[p].
8[s] wherein the processor is electrically coupled to the first electrocardiographic electrode, the second electrocardiographic electrode, and the battery,	***The Accused Instrumentalities include a processor wherein the processor is electrically coupled to the first electrocardiographic electrode, the second electrocardiographic electrode, and the battery.*** The Zio Monitor satisfies 8[s] because the Zio Monitor includes a processor that is electrically coupled to the electrodes and the battery. *See* 1[q].
8[t] wherein the processor is configured to process the electrocardiographic signals sensed via the first electrocardiographic electrode and the second electrocardiographic electrode.	***The Accused Instrumentalities include a processor wherein the processor is configured to process the electrocardiographic signals sensed via the first electrocardiographic electrode and the second electrocardiographic electrode.*** The Zio Monitor satisfies 8[t] because the Zio Monitor processes electrocardiographic signals sensed by its electrocardiographic electrodes. *See* 1[r].

Claim 10	Accused Instrumentalities
10. The wearable electrocardiography monitoring device of Claim 8, wherein the wireless transceiver is configured to communicate with an external device via Wi-Fi, mobile phone communication standards, or Bluetooth.	***The Accused Instrumentalities include the wearable electrocardiography monitoring device of Claim 8, wherein the wireless transceiver is configured to communicate with an external device via Wi-Fi, mobile phone communication standards, or Bluetooth.*** The Zio Monitor satisfies Claim 10 because the Zio Monitor includes a wireless transceiver that communicates with an external device, for example, via Bluetooth. *See* 1[s]; 3; 8[o].

Claim 13	Accused Instrumentalities
13. The wearable electrocardiography monitoring device of Claim 8, wherein the adhesive covering the portion of the first face of the strip is provided on the first end section and the second end section only.	***The Accused Instrumentalities include the wearable electrocardiography monitoring device of Claim 8, wherein the adhesive covering the portion of the first face of the strip is provided on the first end section and the second end section only.*** The Zio Monitor satisfies Claim 13 because the Zio Monitor includes an under side (i.e., a first face) and an upper side (i.e., a second face). *See* 1[b]; 6; 8[b]. The Zio Monitor includes two wing portions that are covered in adhesive to adhere the strip to skin of a patient. *See* 1[b]; 6; 8[b]. Further, the mid-section portion of the Zio Monitor is not covered in adhesive. *See* 1[b]; 6; 8[b].

Claim 15	**Accused Instrumentalities**
15[pre] A wearable electrocardiography monitoring device, comprising:	***To the extent the preamble is deemed to be a limitation, the Accused Instrumentalities include a wearable electrocardiography monitoring device in accordance with this claim.*** The Zio Monitor satisfies 15[pre] because the Zio Monitor is a device that is worn on the patient's body. *See* 1[pre]. In an example, the Zio Monitor monitors patient ECG signals. *See id.*
15[a] a flexible backing including a strip comprising:	***The Accused Instrumentalities include a flexible backing including a strip.*** The Zio Monitor satisfies 15[a] because the Zio Monitor includes a flexible backing including a strip. *See* 1[a].
15[b] a first face and a second face, wherein a portion of the first face is covered in adhesive to adhere the strip to skin of a patient,	***The Accused Instrumentalities include a first face and a second face, wherein a portion of the first face is covered in adhesive to adhere the strip to skin of a patient.*** The Zio Monitor satisfies 15[b] because the Zio Monitor includes an under side (i.e., a first face) and an upper side (i.e., a second face). *See* 1[b]. A portion of the under side is covered in adhesive to adhere the strip to skin of a patient. *See id.*
1[c] a first end section, a second end section opposite the first end section, and a mid-section between the first end section and the second end section, wherein the mid-section is narrower than the first end section and the second end section, and	***The Accused Instrumentalities include a first end section, a second end section opposite the first end section, and a mid-section between the first end section and the second end section.*** The Zio Monitor satisfies 15[c] because the Zio Monitor includes a first end section that is opposite a second end section. *See* 1[c]. The Zio Monitor also includes a mid-section between the first end section and the second end section. *See id.*
15[d] wherein the mid-section comprises a first edge parallel to a second edge;	***The Accused Instrumentalities include a mid-section wherein the mid-section is narrower than the first end section and the second end section, and wherein the mid-section comprises a first edge parallel to a second edge.*** The Zio Monitor satisfies 15[d] because the Zio Monitor includes a mid-

Claim 15	**Accused Instrumentalities**
	section that is narrower than each end section. *See, e.g.*, 1[c]; *see also* 8[d]. The mid-section has two edges (i.e., a first edge and a second edge) that are parallel to each other. *See, e.g.*, 1[c]; *see also* 8[d].
15[e] a flexible circuit mounted to the second face of the strip, the flexible circuit comprising a first circuit trace and a second circuit trace;	***The Accused Instrumentalities include a flexible circuit mounted to the second face of the strip, the flexible circuit comprising a first circuit trace and a second circuit trace.*** The Zio Monitor satisfies 15[e] because the Zio Monitor includes a flexible circuit comprising two circuit traces (i.e., a first circuit trace and a second circuit trace). *See* 1[d]. The flexible circuit is mounted to the upper side of the strip (i.e., second face). *See id.*
15[f] a first electrocardiographic electrode and a second electrocardiographic electrode,	***The Accused Instrumentalities include a first electrocardiographic electrode and a second electrocardiographic electrode.*** The Zio Monitor satisfies 15[f] because the Zio Monitor includes two elecrocardiographic electrodes. *See* 1[e].
15[g] wherein the first electrocardiographic electrode and the second electrocardiographic electrode are configured to sense electrocardiographic signals,	***The Accused Instrumentalities include wherein the first electrocardiographic electrode and the second electrocardiographic electrode are configured to sense electrocardiographic signals.*** The Zio Monitor satisfies 15[g] because the Zio Monitor includes two electrocardiographic electrodes that sense electrocardiographic signals. *See* 1[f].
15[h] wherein the first electrocardiographic electrode and the second electrocardiographic electrode are coupled to the flexible circuit,	***The Accused Instrumentalities include wherein the first electrocardiographic electrode and the second electrocardiographic electrode are coupled to the flexible circuit.*** The Zio Monitor satisfies 15[h] because the Zio Monitor has electrocardiographic electrodes that are coupled to the flexible circuit. *See* 1[g].
15[i] wherein the first electrocardiographic electrode is conductively	***The Accused Instrumentalities include wherein the first electrocardiographic electrode is conductively exposed at the first face along the first end section of the strip.*** The Zio Monitor satisfies 15[i] because the Zio Monitor includes an electrocardiographic electrode conductively

Claim 15	**Accused Instrumentalities**
exposed at the first face along the first end section of the strip,	exposed on the upper side (i.e., the first face) along one end (i.e., the first end section) of the strip. *See* 1[h].
15[j] wherein the second electrocardiographic electrode is conductively exposed at the first face along the second end section of the strip,	***The Accused Instrumentalities include wherein the second electrocardiographic electrode is conductively exposed at the first face along the second end section of the strip.*** The Zio Monitor satisfies 15[j] because the Zio Monitor includes an electrocardiographic electrode conductively exposed on the upper side (i.e., the first face) along one end (i.e., the second end section) of the strip. *See* 1[i].
15[k] wherein the first circuit trace is electrically coupled to the first electrocardiographic electrode,	***The Accused Instrumentalities include wherein the first circuit trace is electrically coupled to the first electrocardiographic electrode.*** The Zio Monitor satisfies 15[k] because the Zio Monitor includes circuit traces, one of which is electrically coupled to one of the electrocardiographic electrodes (i.e., the first electrocardiographic electrode). *See* 1[j].
15[l] wherein the second circuit trace is electrically coupled to the second electrocardiographic electrode, and	***The Accused Instrumentalities include wherein the second circuit trace is electrically coupled to the second electrocardiographic electrode.*** The Zio Monitor satisfies 15[l] because the Zio Monitor includes circuit traces, one of which is coupled to one of the electrocardiographic electrodes (i.e., the second electrocardiographic electrode). *See* 1[k].
15[m] wherein the first electrocardiographic electrode includes an inline resistor;	***The Accused Instrumentalities include wherein the first electrocardiographic electrode includes an inline resistor.*** The Zio Monitor satisfies 15[m] because the Zio Monitor includes an inline resistor located on the flexible backing. *See* 1[l]. Further, the inline resister is integrated into the ECG tracings. *See id.*
15[n] a battery vertically aligned with a sealed housing,	***The Accused Instrumentalities include a battery vertically aligned with a sealed housing.*** The Zio Monitor satisfies 15[n] because the Zio Monitor includes a battery. *See* 1[m]. The battery powers the body worn device. The battery is located in and vertically aligned with a sealed housing. *See id.*
15[o] wherein the sealed housing includes rounded edges on a top surface,	***The Accused Instrumentalities includes wherein the sealed housing includes rounded edges on a top surface.*** The Zio Monitor satisfies 15[o] because the Zio Monitor includes a sealed housing with rounded edges on its top surface. *See* 1[n].

Claim 15	**Accused Instrumentalities**
15[p] wherein the sealed housing is coupled to the flexible backing, and	***The Accused Instrumentalities include a sealed housing wherein the sealed housing is coupled to the flexible backing.*** The Zio Monitor satisfies 15[p] because the Zio Monitor includes a sealed housing that is coupled to the flexible backing. *See* 1[o].
15[q] wherein the sealed housing includes a processor,	***The Accused Instrumentalities include a sealed housing wherein the sealed housing includes a processor.*** The Zio Monitor satisfies 15[q] because the Zio Monitor has a processer in its sealed housing. *See* 1[p].
15[r] wherein the processor is electrically coupled to the first electrocardiographic electrode, the second electrocardiographic electrode, and the battery,	***The Accused Instrumentalities include a processor wherein the processor is electrically coupled to the first electrocardiographic electrode, the second electrocardiographic electrode, and the battery.*** The Zio Monitor satisfies 15[r] because the Zio Monitor includes a processor that is electrically coupled to the electrodes and the battery. *See* 1[q].
15[s] wherein the processor is configured to process the electrocardiographic signals sensed via the first electrocardiographic electrode and the second electrocardiographic electrode; and	***The Accused Instrumentalities include a processor wherein the processor is configured to process the electrocardiographic signals sensed via the first electrocardiographic electrode and the second electrocardiographic electrode.*** The Zio Monitor satisfies 15[s] because the Zio Monitor processes electrocardiographic signals sensed by its electrocardiographic electrodes. *See* 1[r].
15[t] a wireless transceiver, wherein the wireless transceiver draws power from the battery.	***The Accused Instrumentalities include a wireless transceiver.*** The Zio Monitor satisfies 15[t] because the Zio Monitor includes a wireless transceiver and a battery. *See* 1[s]. The wireless transceiver draws power from the battery. *See* 1[s].

Claim 16	**Accused Instrumentalities**
16. The wearable electrocardiography monitoring device of Claim 15, wherein the wireless transceiver is configured to communicate with an external device via Wi-Fi, mobile phone communication standards, or Bluetooth.	***The Accused Instrumentalities includes the wearable electrocardiography monitoring device of Claim 15, wherein the wireless transceiver is configured to communicate with an external device via Wi-Fi, mobile phone communication standards, or Bluetooth.*** The Zio Monitor satisfies Claim 16 because the Zio Monitor includes a wireless transceiver that communicates with an external device, for example, via Bluetooth. *See* 1[s]; 15[t]. The wireless transceiver draws power from the battery. *See* 1[s]; 15[t].

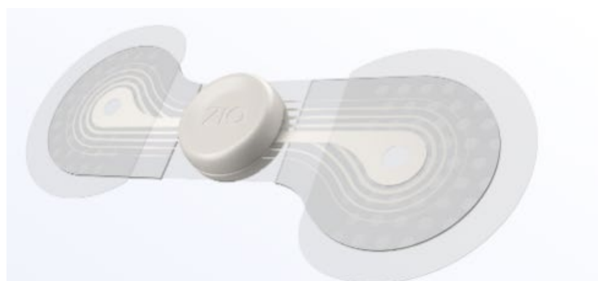
Claim 19	**Accused Instrumentalities**
19. The wearable electrocardiography monitoring device of Claim 15, wherein the adhesive covering the portion of the first face of the strip is provided on the first end section and the second end section only.	***The Accused Instrumentalities include the wearable electrocardiography monitoring device of Claim 15, wherein the adhesive covering the portion of the first face of the strip is provided on the first end section and the second end section only.*** The Zio Monitor satisfies Claim 19 because the Zio Monitor includes an under side (i.e., a first face) and an upper side (i.e., a second face). *See* 1[b]; 6; 8[b]. The Zio Monitor includes two wing portions that are covered in adhesive to adhere the strip to skin of a patient. *See* 1[b]; 6; 8[b]. Further, the mid-section portion of the Zio Monitor is not covered in adhesive. *See* 1[b]; 6; 8[b].

EXHIBIT 15

Claim Chart for U.S. Patent No. 12,171,562 ("the '562 Patent")

The Accused Instrumentalities include, but are not necessarily limited to, the Next-generation Zio Monitor by iRhythm (the "Zio Monitor"). The Accused Instrumentalities infringe the identified claims of the '562 Patent, as described below, either directly under 35 U.S.C. § 271(a), or indirectly under 35 U.S.C. §§ 271(b)–(c). The Accused Instrumentalities infringe such claims literally and, to the extent not literally, under the doctrine of equivalents.

Claim 8	**Accused Instrumentalities**
8[pre] A wearable electrocardiography monitoring device, comprising:	***To the extent the preamble is deemed to be a limitation, the Accused Instrumentalities include a wearable electrocardiography monitoring device in accordance with this claim.*** The Zio Monitor satisfied 8[pre] because the Zio Monitor is a device that is worn on the patient's body. In an example, the Zio Monitor monitors patient ECG signals.  Zio Monitor (https://go.irhythmtech.com/hubfs/LB10117.01%20-%20ZIO%20MONITOR%20INSTRUCTIONS%20FOR%20USE%2c%20PRINTED%20(2).pdf)

Claim 8	Accused Instrumentalities
	ZIO MONITOR SYSTEM The Zio Monitor System is the next generation of the Zio XT System, and is a prescription-only, remote ECG monitoring system that consists of the Zio Monitor patch that records the electric signal from the heart continuously for up to 14 days and the ZEUS System, which supports the capture and analysis of ECG data recorded by the Zio Monitor patch at the end of the wear period, including specific arrhythmia events detected by the ZEUS algorithm. (https://go.irhythmtech.com/hubfs/LB10117.01%20-%20ZIO%20MONITOR%20INSTRUCTIONS%20FOR%20USE%2c%20PRINTED%20(2).pdf)  **Next-generation Zio® monitor** Long-Term Continuous Monitoring Service Introducing the Zio monitor—designed to be lighter, smaller, and thinner, while building on the high performance of Zio XT.[5-8] (https://www.irhythmtech.com/providers/zio-service/zio-monitors)

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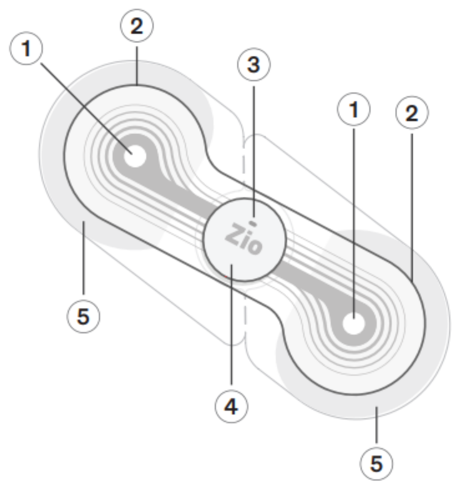
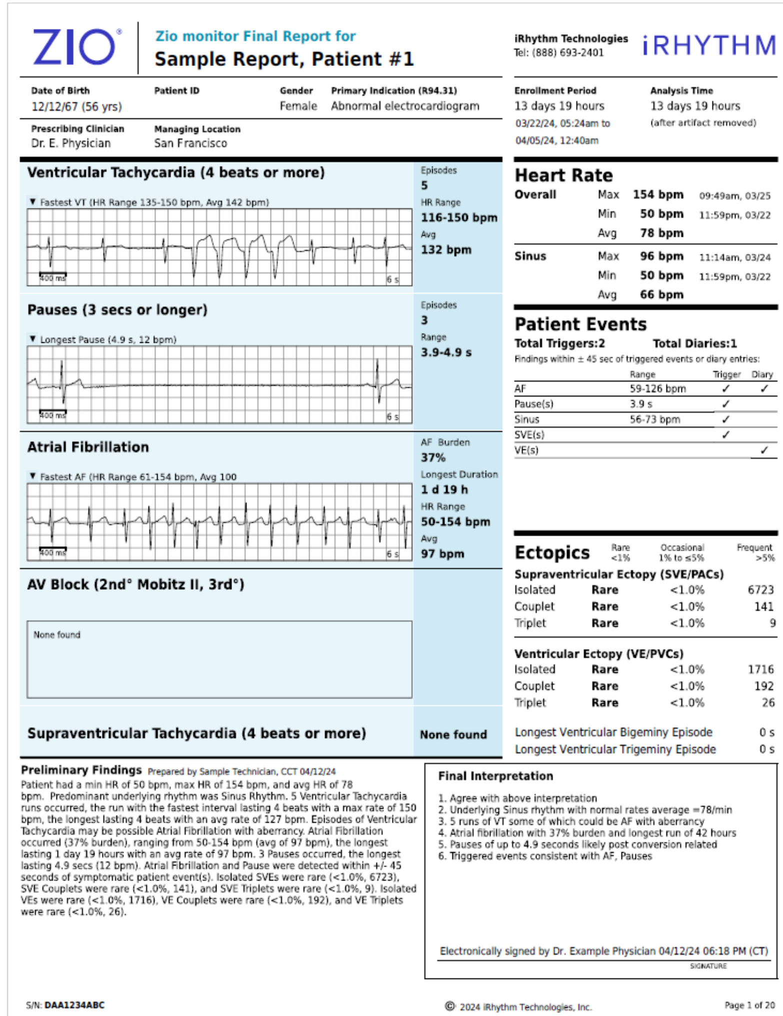
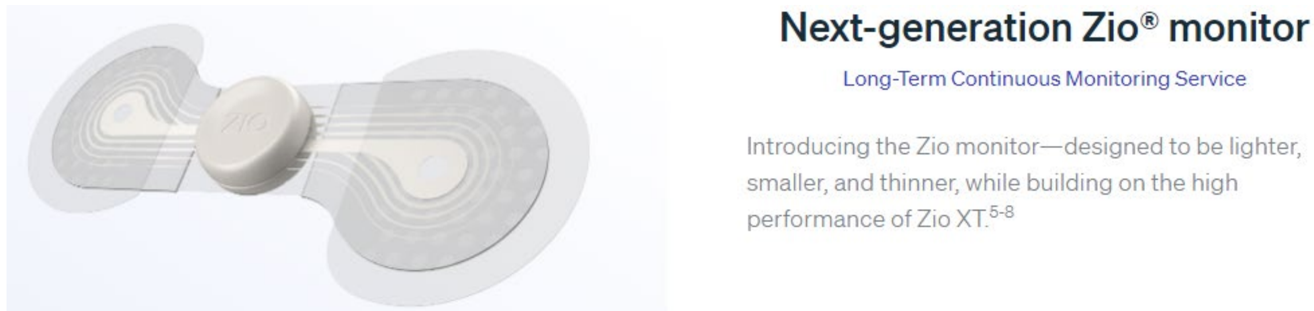
Claim 8	**Accused Instrumentalities**
	Zio Monitor Zio XT Zio AT Long-term continuous monitoring service The new Zio monitor is designed with patients in mind by providing a more breathable, inconspicuous, and comfortable wear experience so patients can go about their daily activities.[5,15,16] (https://www.irhythmtech.com/providers/zio-service/zio-monitors) Example of Zio monitor  1 Electrode – acquires ECG data 2 Adhesive wings – adheres the Zio monitor to the upper-left chest 3 Light – momentarily flashes green when activated and orange in the event of an error. After activation, you will not see any lights. Refer to Troubleshooting - flashing lights on page 17. 4 Zio button – activates the Zio monitor. The patient presses this button when a symptom is felt. 5 Clear plastic backings – remove from back of Zio monitor and discard before applying to the chest. (https://go.irhythmtech.com/hubfs/LB10117.01%20-%20ZIO%20MONITOR%20INSTRUCTIONS%20FOR%20USE%2c%20PRINTED%20(2).pdf)

Claim 8	Accused Instrumentalities
	The Zio monitor is a single-use ECG monitor that provides a continuous, single-channel recording for up to 14 days. The Zio monitor records ECG data without patient interaction, with the goal of improving patient compliance via simplicity of operation. Patients have the option of pressing a convenient button and filling out a log to document symptomatic events, which will support symptom-rhythm correlation in the diagnostic report. (https://go.irhythmtech.com/hubfs/LB10117.01%20-%20ZIO%20MONITOR%20INSTRUCTIONS%20FOR%20USE%2c%20PRINTED%20(2).pdf) **Intended use** The Zio monitor is intended to capture symptomatic and asymptomatic cardiac events in a continuous electrocardiogram record for long-term monitoring. **Indications for use** The Zio monitor is a prescription-only, single-use ECG monitor that continuously records data for up to 14 days. It is indicated for use on patients who may be asymptomatic or who may suffer from transient symptoms such as palpitations, shortness of breath, dizziness, lightheadedness, pre-syncope, syncope, fatigue, or anxiety. (https://go.irhythmtech.com/hubfs/LB10117.01%20-%20ZIO%20MONITOR%20INSTRUCTIONS%20FOR%20USE%2c%20PRINTED%20(2).pdf)

Claim 8	**Accused Instrumentalities**
	 ZIO® Zio monitor Final Report for Sample Report, Patient #1 — iRhythm Technologies Tel: (888) 693-2401 iRHYTHM Date of Birth 12/12/67 (56 yrs) · Patient ID · Gender Female · Primary Indication (R94.31) Abnormal electrocardiogram · Prescribing Clinician Dr. E. Physician · Managing Location San Francisco · Enrollment Period 13 days 19 hours 03/22/24, 05:24am to 04/05/24, 12:40am · Analysis Time 13 days 19 hours (after artifact removed) **Ventricular Tachycardia (4 beats or more)** — Fastest VT (HR Range 135-150 bpm, Avg 142 bpm) — Episodes 5; HR Range 116-150 bpm; Avg 132 bpm **Pauses (3 secs or longer)** — Longest Pause (4.9 s, 12 bpm) — Episodes 3; Range 3.9-4.9 s **Atrial Fibrillation** — Fastest AF (HR Range 61-154 bpm, Avg 100 — AF Burden 37%; Longest Duration 1 d 19 h; HR Range 50-154 bpm; Avg 97 bpm **AV Block (2nd° Mobitz II, 3rd°)** — None found **Supraventricular Tachycardia (4 beats or more)** — None found **Heart Rate** — Overall: Max 154 bpm 09:49am, 03/25; Min 50 bpm 11:59pm, 03/22; Avg 78 bpm. Sinus: Max 96 bpm 11:14am, 03/24; Min 50 bpm 11:59pm, 03/22; Avg 66 bpm **Patient Events** — Total Triggers:2 Total Diaries:1 — Findings within ± 45 sec of triggered events or diary entries: AF 59-126 bpm ✓ ✓; Pause(s) 3.9 s ✓; Sinus 56-73 bpm ✓; SVE(s) ✓; VE(s) ✓ **Ectopics** (Rare <1%, Occasional 1% to ≤5%, Frequent >5%) — Supraventricular Ectopy (SVE/PACs): Isolated Rare <1.0% 6723; Couplet Rare <1.0% 141; Triplet Rare <1.0% 9. Ventricular Ectopy (VE/PVCs): Isolated Rare <1.0% 1716; Couplet Rare <1.0% 192; Triplet Rare <1.0% 26. Longest Ventricular Bigeminy Episode 0 s; Longest Ventricular Trigeminy Episode 0 s **Preliminary Findings** Prepared by Sample Technician, CCT 04/12/24 — Patient had a min HR of 50 bpm, max HR of 154 bpm, and avg HR of 78 bpm. Predominant underlying rhythm was Sinus Rhythm. 5 Ventricular Tachycardia runs occurred, the run with the fastest interval lasting 4 beats with a max rate of 150 bpm, the longest lasting 4 beats with an avg rate of 127 bpm. Episodes of Ventricular Tachycardia may be possible Atrial Fibrillation with aberrancy. Atrial Fibrillation occurred (37% burden), ranging from 50-154 bpm (avg of 97 bpm), the longest lasting 1 day 19 hours with an avg rate of 97 bpm. 3 Pauses occurred, the longest lasting 4.9 secs (12 bpm). Atrial Fibrillation and Pause were detected within +/- 45 seconds of symptomatic patient event(s). Isolated SVEs were rare (<1.0%, 6723), SVE Couplets were rare (<1.0%, 141), and SVE Triplets were rare (<1.0%, 9). Isolated VEs were rare (<1.0%, 1716), VE Couplets were rare (<1.0%, 192), and VE Triplets were rare (<1.0%, 26). **Final Interpretation** — 1. Agree with above interpretation 2. Underlying Sinus rhythm with normal rates average =78/min 3. 5 runs of VT some of which could be AF with aberrancy 4. Atrial fibrillation with 37% burden and longest run of 42 hours 5. Pauses of up to 4.9 seconds likely post conversion related 6. Triggered events consistent with AF, Pauses — Electronically signed by Dr. Example Physician 04/12/24 06:18 PM (CT) SIGNATURE S/N: DAA1234ABC · © 2024 iRhythm Technologies, Inc. · Page 1 of 20 (https://www.irhythmtech.com/providers/zio-service/reporting)

Claim 8	**Accused Instrumentalities**
8[a] a flexible backing including a strip comprising:	***The Accused Instrumentalities include a flexible backing including a strip.*** The Zio Monitor satisfied 8[a] because the Zio Monitor includes a flexible backing including a strip. The new Zio monitor: The new Zio monitor is designed to be effortless to wear with increased adherence and better patient comfort. It's small enough for patients to forget they are wearing it through exercise, showering, and sleeping. The new design is more than 50% lighter than the current generation, and includes a new breathable and waterproof outer layer. It also has an improved 'stay-put' adhesive and a more flexible design for a secure attachment. These refinements will allow for a more comfortable wear and, therefore, more complete, accurate diagnostic data. (https://www.irhythmtech.com/company/news/irhythm-technologies-continues-to-fuel-innovation-in-cardiac-monitoring-and-unveils-two-fda-clearances-for-superior-patient-care) The Zio patches include the following features: • patented flexible, lightweight, wire-free design; • unobtrusive and inconspicuous profile; • proprietary adhesive backing designed to keep the Zio patch securely in place for the duration of the prescribed wear period; (https://go.irhythmtech.com/hubfs/LB10117.01%20-%20ZIO%20MONITOR%20INSTRUCTIONS%20FOR%20USE%2c%20PRINTED%20(2).pdf) wearable medical device and a biosensor onto that small form factor. So, miniaturization was focused on very clever ways of handling some of the larger components, which for example involved moving some of the big resistors that are required on the device to the more flexible part of the patch instead of on the actual printed circuit board in the housing. And this is a patented feature that we've already

Claim 8	**Accused Instrumentalities**
	(https://www.mddionline.com/cardiovascular/behind-the-design-how-irhythm-built-its-new-zio-monitor)  Zio Monitor (https://go.irhythmtech.com/hubfs/LB10117.01%20-%20ZIO%20MONITOR%20INSTRUCTIONS%20FOR%20USE%2c%20PRINTED%20(2).pdf)

<table>
<tr><th><u>Claim 8</u></th><th><u>Accused Instrumentalities</u></th></tr>
<tr><td></td><td>


(https://www.irhythmtech.com/providers/zio-service/zio-monitors)
</td></tr>
</table>

Claim 8	Accused Instrumentalities
8[b] a first face and a second face, wherein a portion of the first face is covered in adhesive to adhere the strip to skin of a patient,	***The Accused Instrumentalities include a first face and a second face, wherein a portion of the first face is covered in adhesive to adhere the strip to skin of a patient.*** The Zio Monitor satisfies 8[b] because the Zio Monitor includes an underside (*i.e.*, a first face) and an upper side (*i.e.*, a second face). A portion of the underside is covered in adhesive to adhere the strip to skin of a patient.  (Zio Monitor Teardown)  (Zio Monitor Teardown)

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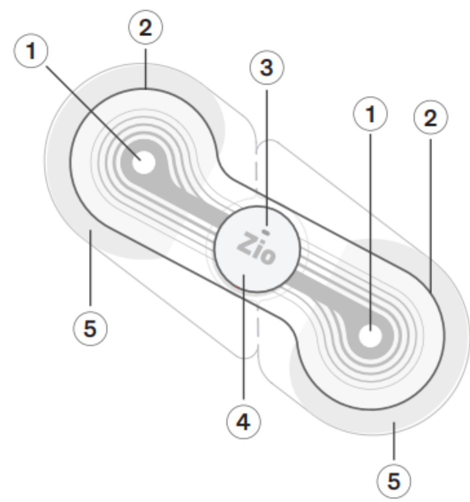
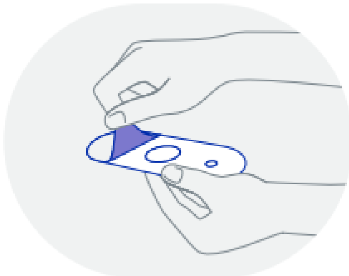
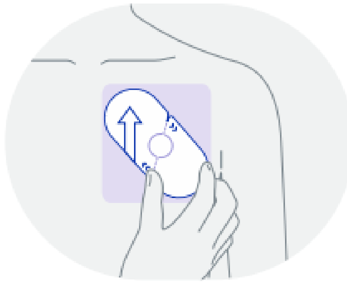
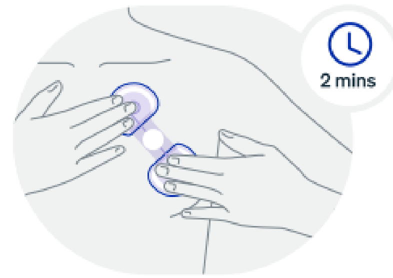
Claim 8	**Accused Instrumentalities**
	Example of Zio monitor  1 Electrode – acquires ECG data 2 Adhesive wings – adheres the Zio monitor to the upper-left chest 3 Light – momentarily flashes green when activated and orange in the event of an error. After activation, you will not see any lights. Refer to Troubleshooting - flashing lights on page 17. 4 Zio button – activates the Zio monitor. The patient presses this button when a symptom is felt. 5 Clear plastic backings – remove from back of Zio monitor and discard before applying to the chest. (https://go.irhythmtech.com/hubfs/LB10117.01%20-%20ZIO%20MONITOR%20INSTRUCTIONS%20FOR%20USE%2c%20PRINTED%20(2).pdf)

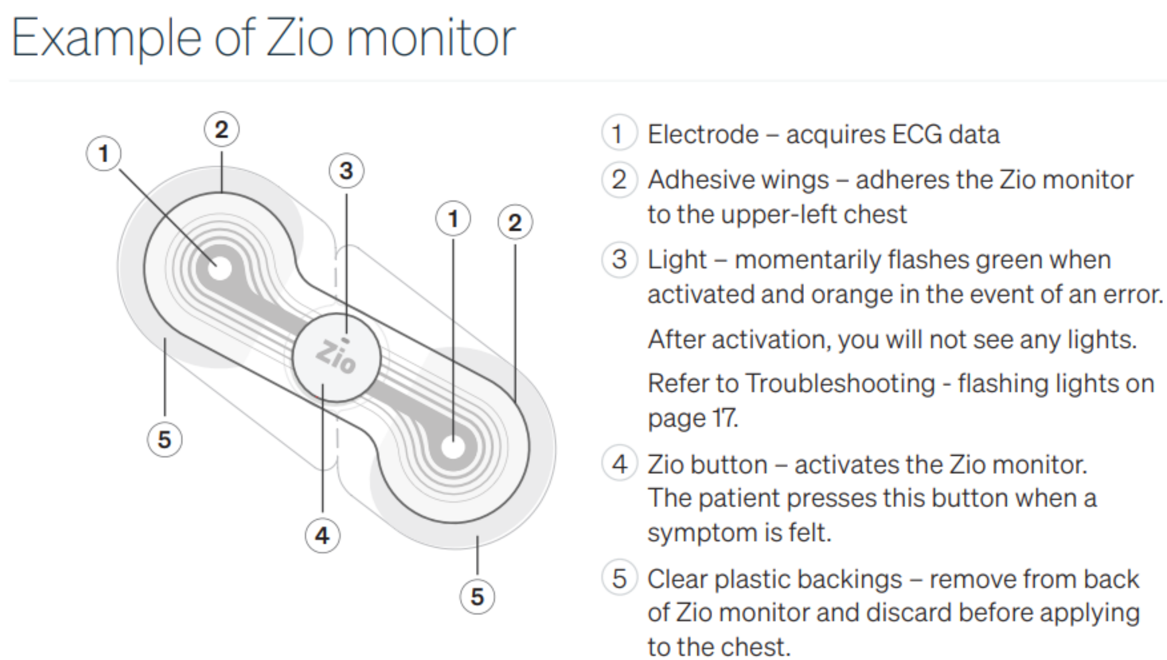
Claim 8	Accused Instrumentalities
	  **2. Peel clear backings:** a. Hold the middle of the Zio monitor. b. Pull off the clear plastic backings carefully and avoid touching the exposed adhesive. c. Keep the paper tabs intact on the other side of the monitor. Note: Wait to remove the paper tabs in Step 5. **3. Apply the Zio monitor:** a. Ensure the white arrow on the paper tab is pointing upward. b. Place the Zio monitor diagonally on the prepared skin area, one finger width below the left collarbone from the center of the upper-left chest. (https://go.irhythmtech.com/hubfs/LB10117.01%20-%20ZIO%20MONITOR%20INSTRUCTIONS%20FOR%20USE%2c%20PRINTED%20(2).pdf)

Claim 8	**Accused Instrumentalities**
	 **6. Massage wings again:** a. Massage the adhesive wings firmly onto the skin for another 2 minutes to prevent the Zio monitor from slipping or falling off the chest. (https://go.irhythmtech.com/hubfs/LB10117.01%20-%20ZIO%20MONITOR%20INSTRUCTIONS%20FOR%20USE%2c%20PRINTED%20(2).pdf) The new Zio monitor: The new Zio monitor is designed to be effortless to wear with increased adherence and better patient comfort. It's small enough for patients to forget they are wearing it through exercise, showering, and sleeping. The new design is more than 50% lighter than the current generation, and includes a new breathable and waterproof outer layer. It also has an improved 'stay-put' adhesive and a more flexible design for a secure attachment. These refinements will allow for a more comfortable wear and, therefore, more complete, accurate diagnostic data. (https://www.irhythmtech.com/company/news/irhythm-technologies-continues-to-fuel-innovation-in-cardiac-monitoring-and-unveils-two-fda-clearances-for-superior-patient-care)

Claim 8	**Accused Instrumentalities**
	The Zio patches include the following features: • patented flexible, lightweight, wire-free design; • unobtrusive and inconspicuous profile; • proprietary adhesive backing designed to keep the Zio patch securely in place for the duration of the prescribed wear period; (https://go.irhythmtech.com/hubfs/LB10117.01%20-%20ZIO%20MONITOR%20INSTRUCTIONS%20FOR%20USE%2c%20PRINTED%20(2).pdf)

<table>
<tr><th><u>Claim 8</u></th><th><u>Accused Instrumentalities</u></th></tr>
<tr><td>8[c] a first end section, a second end section opposite the first end section, and a mid-section between the first end section and the second end section;</td><td>

The Accused Instrumentalities include a first end section, a second end section opposite the first end section, and a mid-section between the first end section and the second end section. The Zio Monitor satisfies 8[c] because the Zio Monitor includes a first end section that is opposite a second end section. The Zio Monitor also includes a mid-section between the first end section and the second end section.



(https://go.irhythmtech.com/hubfs/LB10117.01%20-%20ZIO%20MONITOR%20INSTRUCTIONS%20FOR%20USE%2c%20PRINTED%20(2).pdf)

</td></tr>
</table>

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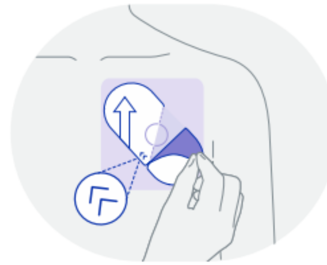
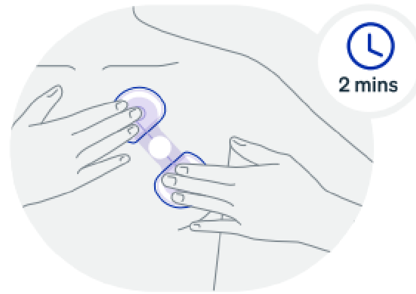
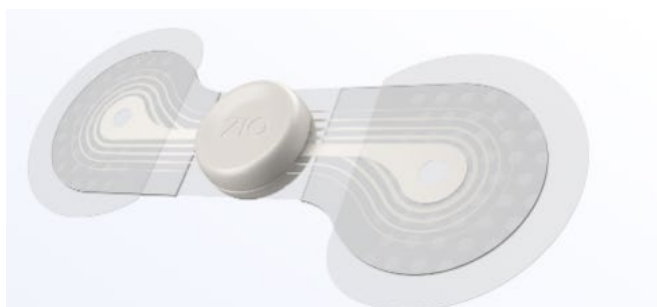
Claim 8	Accused Instrumentalities
	 **5. Remove paper tabs:** a. Find the double arrows located above and below the center of the Zio monitor. b. Peel the tab in the direction of the double arrows. Ensure the adhesive wing does not lift using your other hand. The center of the Zio monitor may slightly lift from the skin as the tab is peeled. c. Remove the remaining tab. (https://go.irhythmtech.com/hubfs/LB10117.01%20-%20ZIO%20MONITOR%20INSTRUCTIONS%20FOR%20USE%2c%20PRINTED%20(2).pdf)

Claim 8	Accused Instrumentalities
	 **6. Massage wings again:** a. Massage the adhesive wings firmly onto the skin for another 2 minutes to prevent the Zio monitor from slipping or falling off the chest. (https://go.irhythmtech.com/hubfs/LB10117.01%20-%20ZIO%20MONITOR%20INSTRUCTIONS%20FOR%20USE%2c%20PRINTED%20(2).pdf)  **Next-generation Zio® monitor** Long-Term Continuous Monitoring Service Introducing the Zio monitor—designed to be lighter, smaller, and thinner, while building on the high performance of Zio XT.[5-8] (https://www.irhythmtech.com/providers/zio-service/zio-monitors)

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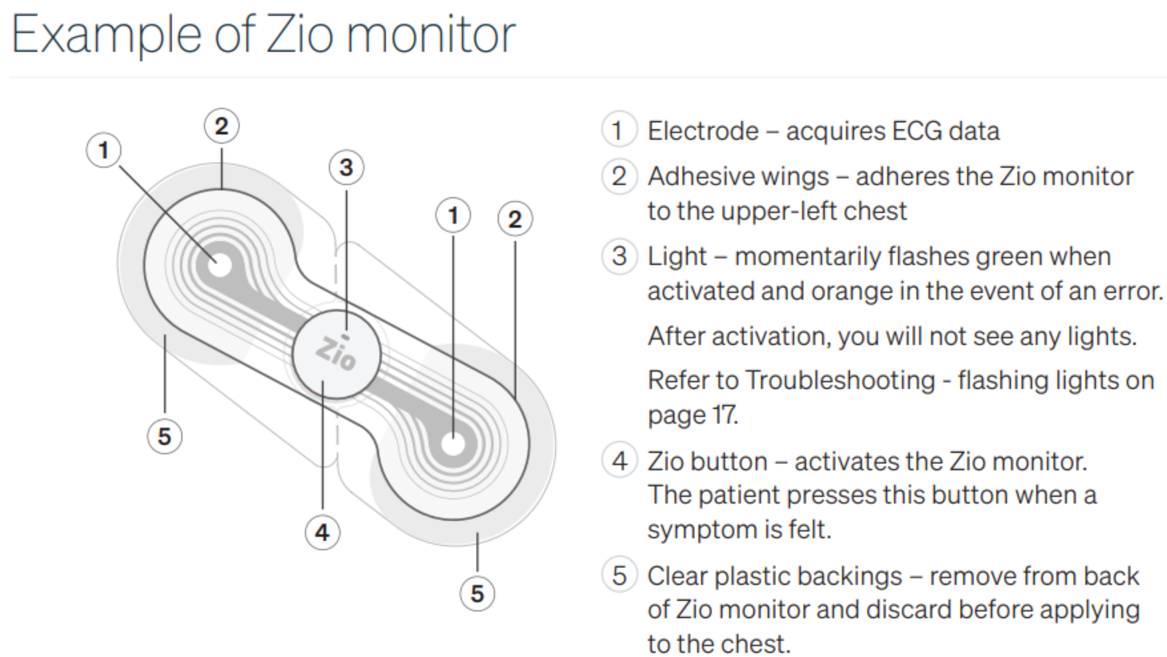
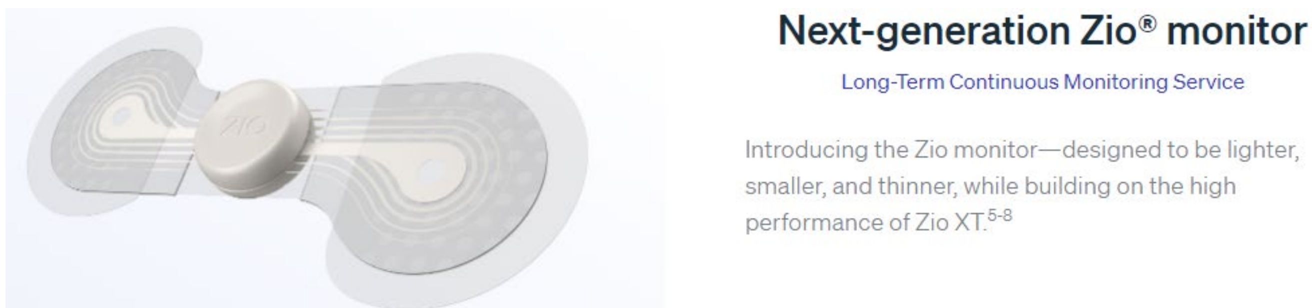
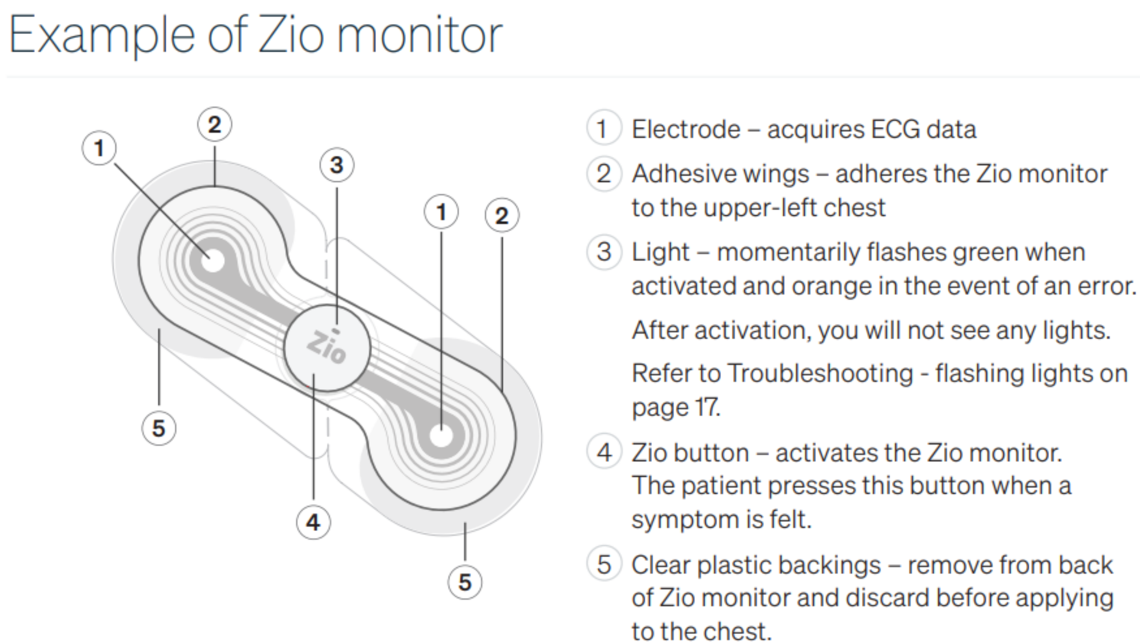
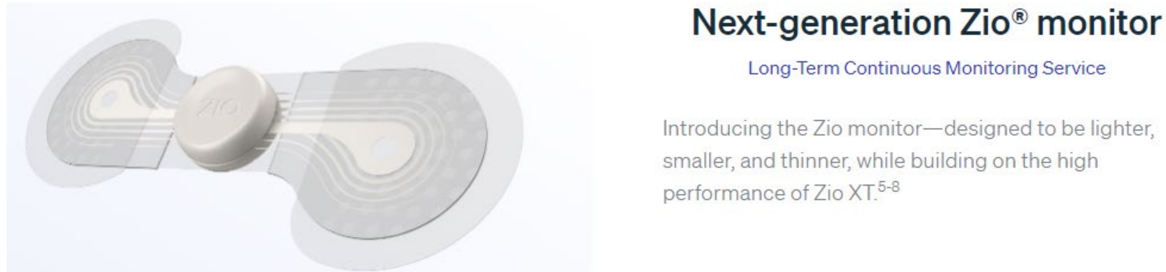
Claim 8	**Accused Instrumentalities**
	 (Zio Monitor Teardown)

Claim 8	Accused Instrumentalities
8[d] wherein the mid-section is narrower than the first end section and the second end section;	***The Accused Instrumentalities include a first end section, a second end section opposite the first end section, and a mid-section between the first end section and the second end section.*** The Zio Monitor satisfies 8[d] because the Zio Monitor includes a mid-section between the first end section and the second end section that is narrower than the first and second end sections as depicted below.  (https://go.irhythmtech.com/hubfs/LB10117.01%20-%20ZIO%20MONITOR%20INSTRUCTIONS%20FOR%20USE%2c%20PRINTED%20(2).pdf)

Claim 8	**Accused Instrumentalities**
	 (Zio Monitor Teardown)  (https://www.irhythmtech.com/providers/zio-service/zio-monitors)

Claim 8	**Accused Instrumentalities**
8[e] a flexible circuit mounted to the second face of the strip, the flexible circuit comprising a first circuit trace and a second circuit trace;	***The Accused Instrumentalities include a flexible circuit mounted to the second face of the strip, the flexible circuit comprising a first circuit trace and a second circuit trace.*** The Zio Monitor satisfies 8[e] because the Zio Monitor includes a flexible circuit comprising two circuit traces (*i.e.*, a first circuit trace and a second circuit trace). The flexible circuit is mounted to the upper side of the strip (*i.e.*, second face).  (https://go.irhythmtech.com/hubfs/LB10117.01%20-%20ZIO%20MONITOR%20INSTRUCTIONS%20FOR%20USE%2c%20PRINTED%20(2).pdf)

<u>**Claim 8**</u>	<u>**Accused Instrumentalities**</u>
	 (https://www.irhythmtech.com/providers/zio-service/zio-monitors)  (Zio Monitor Teardown)

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<table>
<tr><th><u>Claim 8</u></th><th><u>Accused Instrumentalities</u></th></tr>
<tr><td></td><td>

(12) **United States Patent**
Abercrombie, II et al.

(10) **Patent No.: US 11,399,760 B2**
(45) **Date of Patent: *Aug. 2, 2022**

(54) **WEARABLE DEVICE WITH CONDUCTIVE TRACES AND INSULATOR**

(71) Applicant: **iRhythm Technologies, Inc.**, San Francisco, CA (US)

(72) Inventors: **Jeffrey Joseph Abercrombie, II**, Oakland, CA (US); **Genaro Sebastian Sepulveda**, Oakland, CA (US); **Shena Hae Park**, San Francisco, CA (US); **Ryan James Wensley**, San Francisco, CA (US); **James Kihyun Lee**, San Francisco, CA (US); **Thomas Burnell Reeve, III**, San Francisco, CA (US)

(73) Assignee: **IRhythm Technologies, Inc.**, San Francisco, CA (US)

(*) Notice: Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 0 days.
This patent is subject to a terminal disclaimer.

(21) Appl. No.: **17/671,403**

(22) Filed: **Feb. 14, 2022**

(65) **Prior Publication Data**
US 2022/0160279 A1 May 26, 2022

Related U.S. Application Data

(63) Continuation of application No. 17/396,463, filed on Aug. 6, 2021, now Pat. No. 11,246,523.
(Continued)

(51) **Int. Cl.**
A61B 5/00 (2006.01)
A61B 5/257 (2021.01)
(Continued)

(52) **U.S. Cl.**
CPC ***A61B 5/257*** (2021.01); ***A61B 5/282*** (2021.01); ***A61B 5/6833*** (2013.01); ***H05K 1/147*** (2013.01);
(Continued)

(58) **Field of Classification Search**
CPC A61B 5/257; A61B 5/325; A61B 5/6833; A61B 5/6843; A61B 2090/0807;
(Continued)

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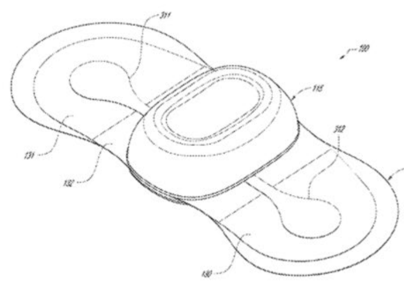
(Continued)

Primary Examiner — Eun Hwa Kim
Assistant Examiner — Adam Z Minchella
(74) *Attorney, Agent, or Firm* — Knobbe, Martens, Olson & Bear, LLP

(57) **ABSTRACT**

The present disclosure relates to a wearable device that includes a housing, battery terminal connector, conductive traces, and an insulator for recording signals. The device may include a housing enclosing a circuit board and a battery. The device may include two conductive traces electrically connected to terminals of the battery and an insulator separating the conductive traces. The battery terminal connector can present both the conductive traces to the outer surface for coupling to a circuit board. The device can assess the physiological signals to infer a likelihood of arrhythmia of a user.

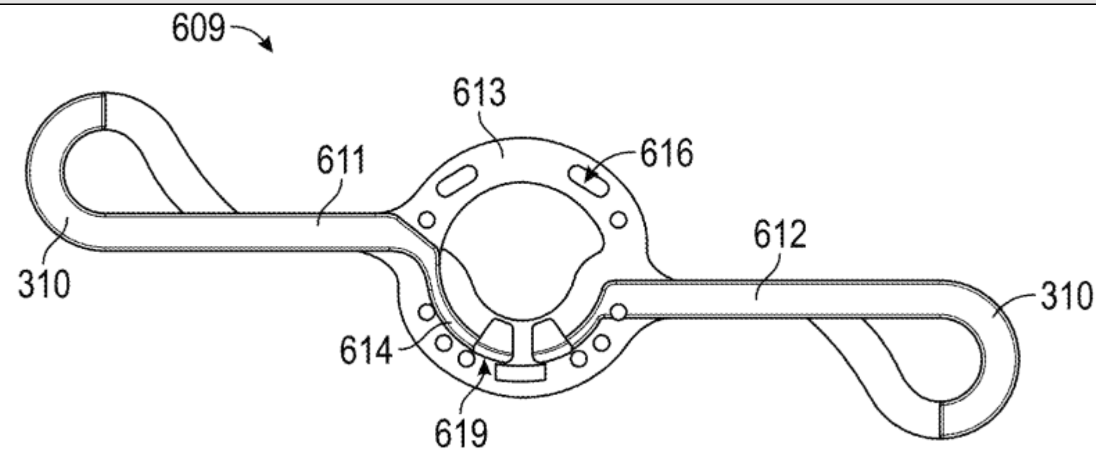
30 Claims, 42 Drawing Sheets



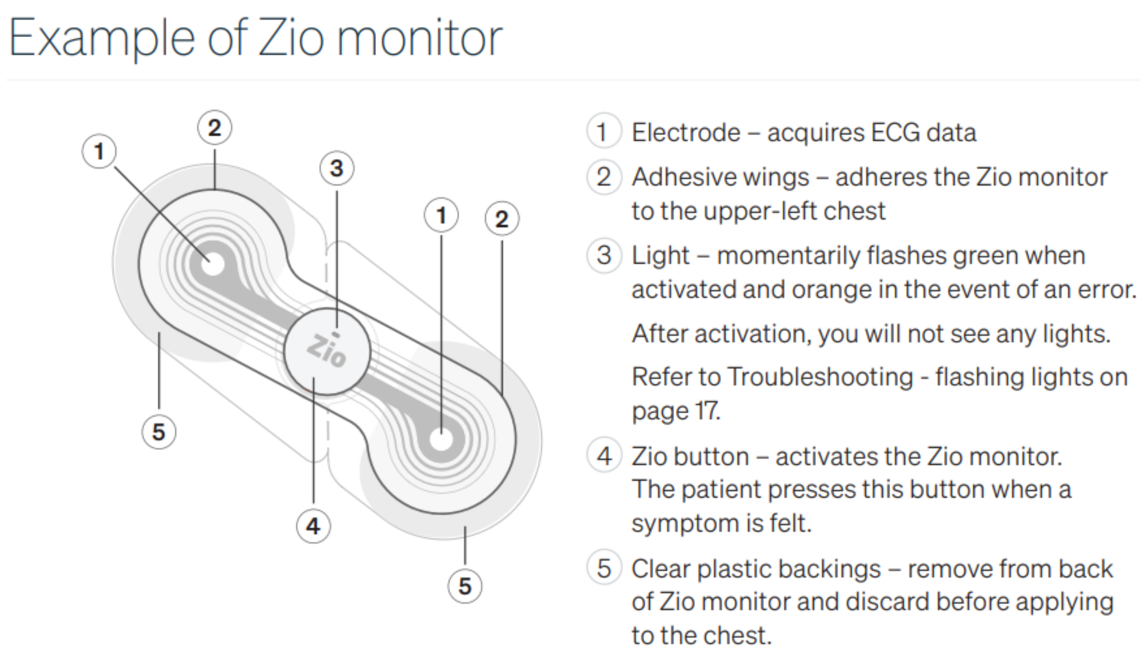
(https://patentimages.storage.googleapis.com/12/7b/34/ee9a6b3db2a824/US11399760.pdf)

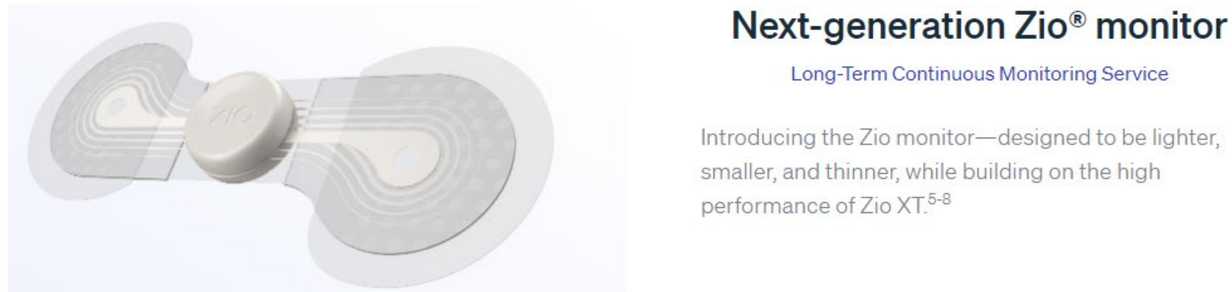
</td></tr>
</table>

Claim 8	**Accused Instrumentalities**
	FIGS. **10A-10C** schematically illustrate alternative examples of trace layer **609**. The trace layer **609** may comprise an electrical trace **611**, **612** for each electrode **350** (such as shown in FIG. **3**B) of the physiological monitoring device **100**. The electrical traces **611**, **612** may be disposed on (e.g., printed onto) a non-conductive insulating layer **613**. In some embodiments, the insulating layer **613** may comprise a polyester, such as polyethylene terephthalate (PET) and/or another non-conductive polymer. One or more of the electrical traces **611**, **612** may be disposed on the same insulating layer **613**. The insulating layer **613** may be configured to maintain a separation between the electrical traces **611**, **612** that are coupled to distinct electrodes **350**. The electrical traces **611**, **612** may extend from the electrodes **350** into the housing **115** to make electrical contact with the PCBA **120**. In some embodiments, such as embodiments in which the physiological monitoring device **100** comprises two opposite wings **130**, **131** arranged generally collinear with one another, the electrical traces **611**, **612** may extend generally collinearly along a direction defining a longitudinal axis of the device. A transverse axis may be defined substantially perpendicular to the longitudinal axis. The longitudinal axis and/or the transverse axis may substantially bisect the housing **115** of the physiological monitoring device **100**. (https://patentimages.storage.googleapis.com/12/7b/34/ee9a6b3db2a824/US11399760.pdf)

Claim 8	Accused Instrumentalities
	 FIG. 10C (https://patentimages.storage.googleapis.com/12/7b/34/ee9a6b3db2a824/US11399760.pdf)

Claim 8	Accused Instrumentalities
	This web page is provided to satisfy the virtual patent marking provisions of various jurisdictions including the virtual patent marking provisions of the America Invents Act and provide notice under 35 U.S.C. §287(a), that the iRhythm Technologies' Zio patch products and related services, including but not limited to the Zio patch, Zio XT, Zio AT, and Zio MCT trademarked products, are covered by or for use under one or more of the patents listed below. Zio patch products and related services are covered by or for use under one or more international patents or international patent applications. Zio patch products and related services not listed here may be protected by one or more patents in the United States and other international jurisdictions and may be covered by patents in the United States and other international jurisdictions that are not listed. iRhythm Technologies' Zio patch products and related services may be sold individually or as part of a combination product or system. US Patent Numbers*: 8,538,503; 8,560,046; 9,173,670; 9,241,649; 9,451,975; 9,597,004; 9,955,887; 10,098,559; 10,271,754; 10,299,691; D852965; D854167; 10,405,799; 10,517,500; 11,141,091; 10,555,683; 11,627,902; 11,051,738; 10,667,712; 10,813,565; 11,605,458; 11,289,197; 11,350,864; 11,350,865; 11,589,792; 11,337,632; 11,504,041; 11,246,523; 11,399,760; 11,246,524; 11,382,555; 11,083,371; 11,253,185; 11,253,186; 11,375,941 and 11,497,432. Additional patents are pending in the United States. (https://www.irhythmtech.com/content/patents-trademarks)

<u>**Claim 8**</u>	<u>**Accused Instrumentalities**</u>
8[f] a first electrocardiographic electrode and a second electrocardiographic electrode,	***The Accused Instrumentalities include a first electrocardiographic electrode and a second electrocardiographic electrode.*** The Zio Monitor satisfies 8[f] because the Zio Monitor includes two elecrocardiographic electrodes.  (https://go.irhythmtech.com/hubfs/LB10117.01%20-%20ZIO%20MONITOR%20INSTRUCTIONS%20FOR%20USE%2c%20PRINTED%20(2).pdf)

Claim 8	**Accused Instrumentalities**
	 (https://www.irhythmtech.com/providers/zio-service/zio-monitors)  (Zio Monitor Teardown)

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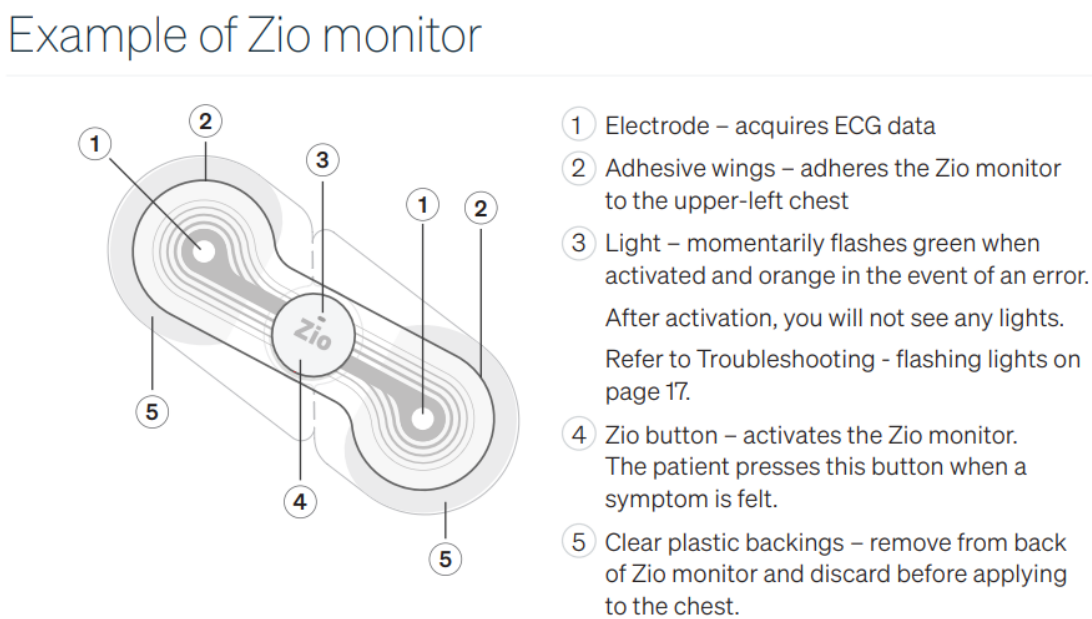
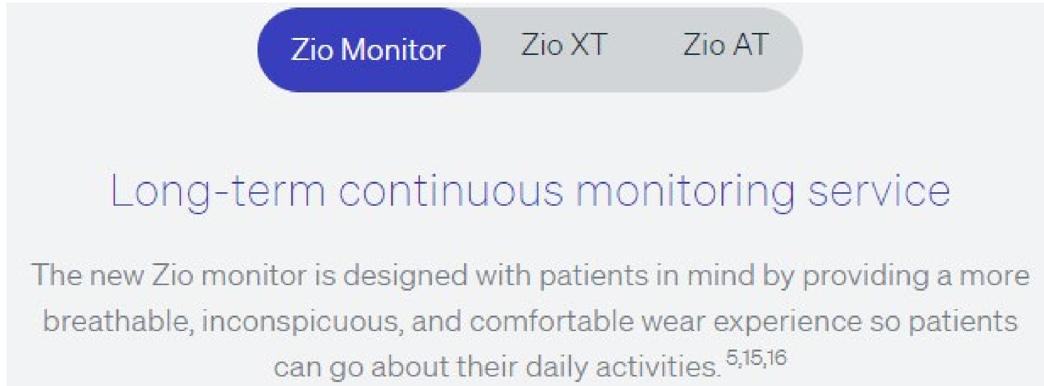
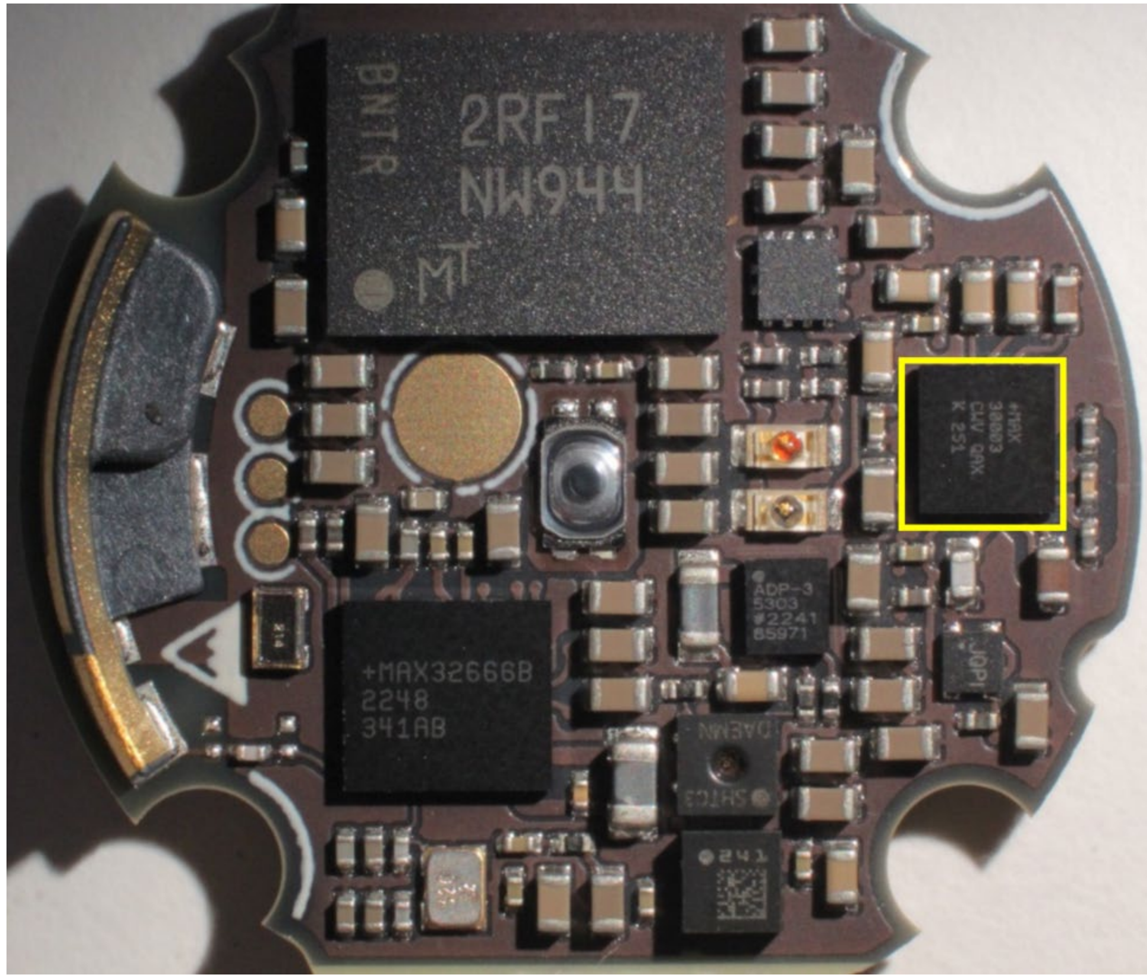
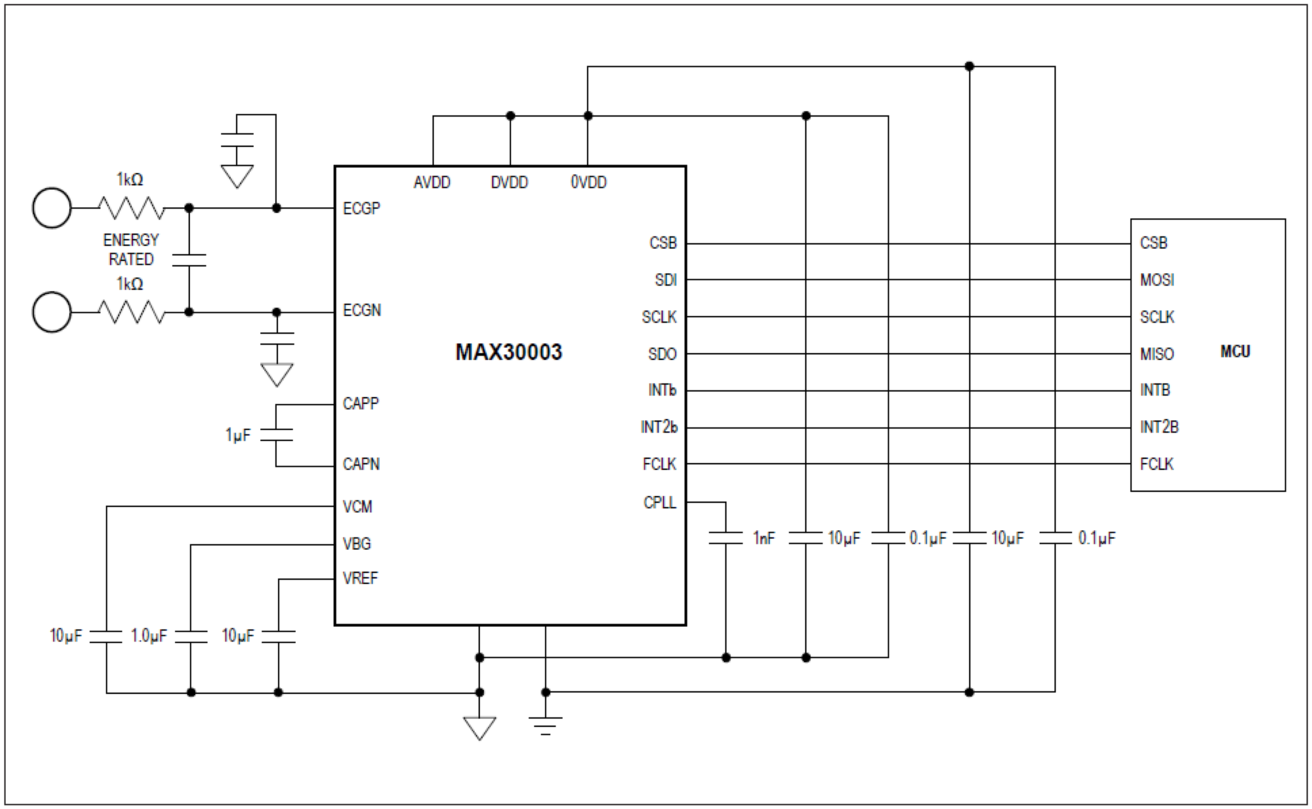
Claim 8	Accused Instrumentalities
8[g] wherein the first electrocardiographic electrode and the second electrocardiographic electrode are configured to sense electrocardiographic signals,	***The Accused Instrumentalities include wherein the first electrocardiographic electrode and the second electrocardiographic electrode are configured to sense electrocardiographic signals.*** The Zio Monitor satisfies 8[g] because the Zio Monitor includes two electrocardiographic electrodes that sense electrocardiographic signals.  (https://go.irhythmtech.com/hubfs/LB10117.01%20-%20ZIO%20MONITOR%20INSTRUCTIONS%20FOR%20USE%2c%20PRINTED%20(2).pdf)

Claim 8	**Accused Instrumentalities**
	The Zio monitor is a single-use ECG monitor that provides a continuous, single-channel recording for up to 14 days. The Zio monitor records ECG data without patient interaction, with the goal of improving patient compliance via simplicity of operation. Patients have the option of pressing a convenient button and filling out a log to document symptomatic events, which will support symptom-rhythm correlation in the diagnostic report. (https://go.irhythmtech.com/hubfs/LB10117.01%20-%20ZIO%20MONITOR%20INSTRUCTIONS%20FOR%20USE%2c%20PRINTED%20(2).pdf) **Intended use** The Zio monitor is intended to capture symptomatic and asymptomatic cardiac events in a continuous electrocardiogram record for long-term monitoring. **Indications for use** The Zio monitor is a prescription-only, single-use ECG monitor that continuously records data for up to 14 days. It is indicated for use on patients who may be asymptomatic or who may suffer from transient symptoms such as palpitations, shortness of breath, dizziness, lightheadedness, pre-syncope, syncope, fatigue, or anxiety. (https://go.irhythmtech.com/hubfs/LB10117.01%20-%20ZIO%20MONITOR%20INSTRUCTIONS%20FOR%20USE%2c%20PRINTED%20(2).pdf)

Claim 8	**Accused Instrumentalities**
	1. Press the button on your Zio monitor when you feel a symptom. • The light does not flash when the button is pressed. • If you forget to either press the button or log a symptom, the Zio monitor is recording the ECG data. (https://go.irhythmtech.com/hubfs/LB10117.01%20-%20ZIO%20MONITOR%20INSTRUCTIONS%20FOR%20USE%2c%20PRINTED%20(2).pdf) The Zio monitor is an ECG monitor that continuously records the electrical activity of the heart. It is intended to be worn continuously for a time period specified by a provider for up to 14 days. (https://go.irhythmtech.com/hubfs/LB10117.01%20-%20ZIO%20MONITOR%20INSTRUCTIONS%20FOR%20USE%2c%20PRINTED%20(2).pdf)

Claim 8	**Accused Instrumentalities**
	 (https://www.irhythmtech.com/providers/zio-service/zio-monitors)

Claim 8	Accused Instrumentalities
	 (Zio Monitor Teardown)

Claim 8	Accused Instrumentalities
	 (MAX30003 Datasheet)

Claim 8	Accused Instrumentalities
	ANALOG DEVICES Evaluation Kit Available · Design Resources · Tools and Models · Support *Click here to ask an associate for production status of specific part numbers.* **Ultra-Low Power, Single-Channel Integrated Biopotential (ECG, R-to-R Detection) AFE** **MAX30003** **General Description** The MAX30003 is a complete, biopotential, analog front-end solution for wearable applications. It offers high performance for clinical and fitness applications, with ultra-low power for long battery life. The MAX30003 is a single biopotential channel providing ECG waveforms and heart rate detection. The biopotential channel has ESD protection, EMI filtering, internal lead biasing, DC leads-off detection, ultra-low power leads-on detection during standby mode, and extensive calibration voltages for built-in self-test. Soft power-up sequencing ensures no large transients are injected into the electrodes. The biopotential channel also has high input impedance, low noise, high CMRR, programmable gain, various low-pass and high-pass filter options, and a high resolution analog-to-digital converter. The biopotential channel is DC coupled, can handle large electrode voltage offsets, and has a fast recovery mode to quickly recover from overdrive conditions, such as defibrillation and electrosurgery. The MAX30003 is available in a 28-pin TQFN and 30-bump wafer-level package (WLP), operating over the 0°C to +70°C commercial temperature range. (MAX30003 Datasheet)

Claim 8	Accused Instrumentalities

	Benefits and Features
	• Clinical-Grade ECG AFE with High-Resolution Data Converter
	  ◦ 15.5 Bits Effective Resolution with $5\mu V_{P-P}$ Noise
	• Better Dry Starts Due to Much Improved Real World CMRR and High Input Impedance
	  ◦ Fully Differential Input Structure with CMRR > 100dB
	• Offers Better Common-Mode to Differential Mode Conversion Due to High Input Impedance
	  ◦ High Input Impedance > 500MΩ for Extremely Low Common-to-Differential Mode Conversion
	• Minimum Signal Attenuation at the Input During Dry Start Due to High Electrode Impedance
	• High DC Offset Range of ±650mV (1.8V, typ) Allows to Be Used with Wide Variety of Electrodes
	• High AC Dynamic Range of $65mV_{P-P}$ Will Help the AFE Not Saturate in the Presence of Motion/Direct Electrode Hits
	• Longer Battery Life Compared to Competing Solutions
	  ◦ 85µW at 1.1V Supply Voltage
	• Leads-On Interrupt Feature Allows to Keep µC in Deep Sleep Mode with RTC Off Until Valid Lead Condition is Detected
	  ◦ Lead-On Detect Current: 0.7µA (typ)
	
	(MAX30003 Datasheet)

Claim 8	Accused Instrumentalities
	• Built-In Heart Rate Detection with Interrupt Feature Eliminates the Need to Run HR Algorithm on the µController • Robust R-R Detection in High Motion Environment at Extremely Low Power • Configurable Interrupts Allows the µC Wake-Up Only on Every Heart Beat Reducing the Overall System Power • High Accuracy Allows for More Physiological Data Extractions • 32-Word FIFO Allows You to Wake Up µController Every 256ms with Full ECG Acquisition • High-Speed SPI Interface • Shutdown Current of 0.5µA (typ) (MAX30003 Datasheet) **R-to-R Detection** The MAX30003 contains built-in hardware to detect R-R intervals using an adaptation of the Pan-Tompkins QRS detection algorithm[1]. The timing resolution of the R-R interval is approximately 8ms and depends on the setting of FMSTR [1:0] in CNFG_GEN (0x10) register. See Table 22 for the timing resolution of each setting. (MAX30003 Datasheet)

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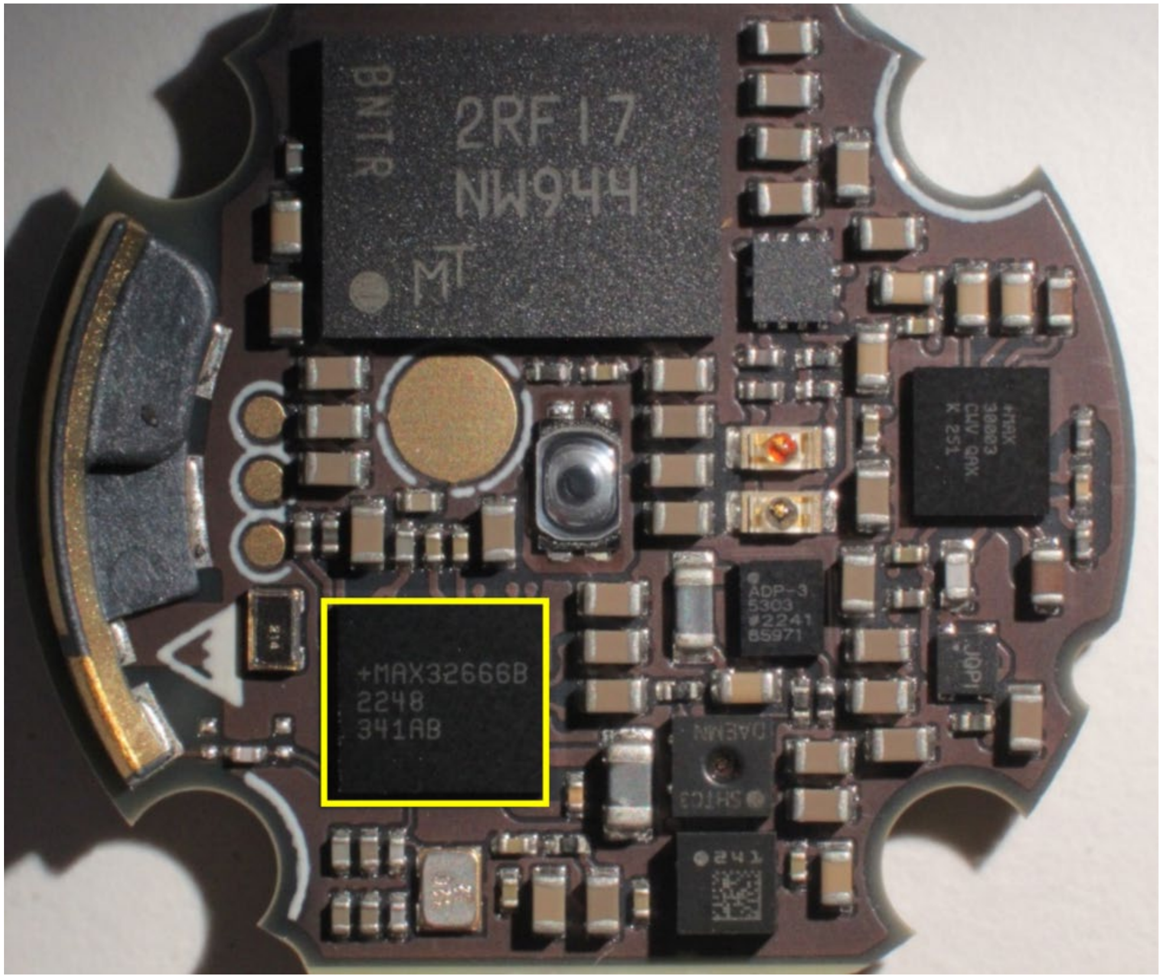
Claim 8	Accused Instrumentalities
	 (Zio Monitor Teardown)

Claim 8	**Accused Instrumentalities**
	ANALOG DEVICES Click here to ask an associate for production status of specific part numbers. MAX32665/MAX32666 Low-Power Arm Cortex-M4 with FPU-Based Microcontroller with Bluetooth 5 for Wearables **General Description** DARWIN is a new breed of low-power microcontrollers built to thrive in the rapidly evolving Internet of Things (IoT). They are smart, with the biggest memories in their class and a massively scalable memory architecture. They run forever, thanks to wearable-grade power technology. They are durable enough to withstand the most advanced cyberattacks. DARWIN microcontrollers are designed to run any application imaginable—in places where you would not dream of sending other microcontrollers. Generation UB microcontrollers are designed to handle the increasingly complex applications demanded by today's advanced battery-powered devices and wirelessly connected devices, while providing robust hardware security and Bluetooth® 5 Low Energy (Bluetooth LE) radio connectivity. The MAX32665/MAX32666 UB class microcontrollers are advanced systems-on-chips featuring an Arm® Cortex®-M4 with FPU CPU for efficient computation of complex functions and algorithms with integrated power management. It also includes the newest generation Bluetooth 5 LE radio with support for long range (4x) and high throughput (2Mbps) and ADI's best-in-class hardware security suite trust protection unit (TPU). The devices offer large on-board memory with 1MB flash and 560KB SRAM. Split flash banks of 512KB each support seamless over-the-air upgrades, adding an additional degree of reliability. Memory scalability of data (SRAM) and code (Flash) space is supported by two SPI execute-in-place (SPIX) interfaces. (MAX32666 Datasheet)

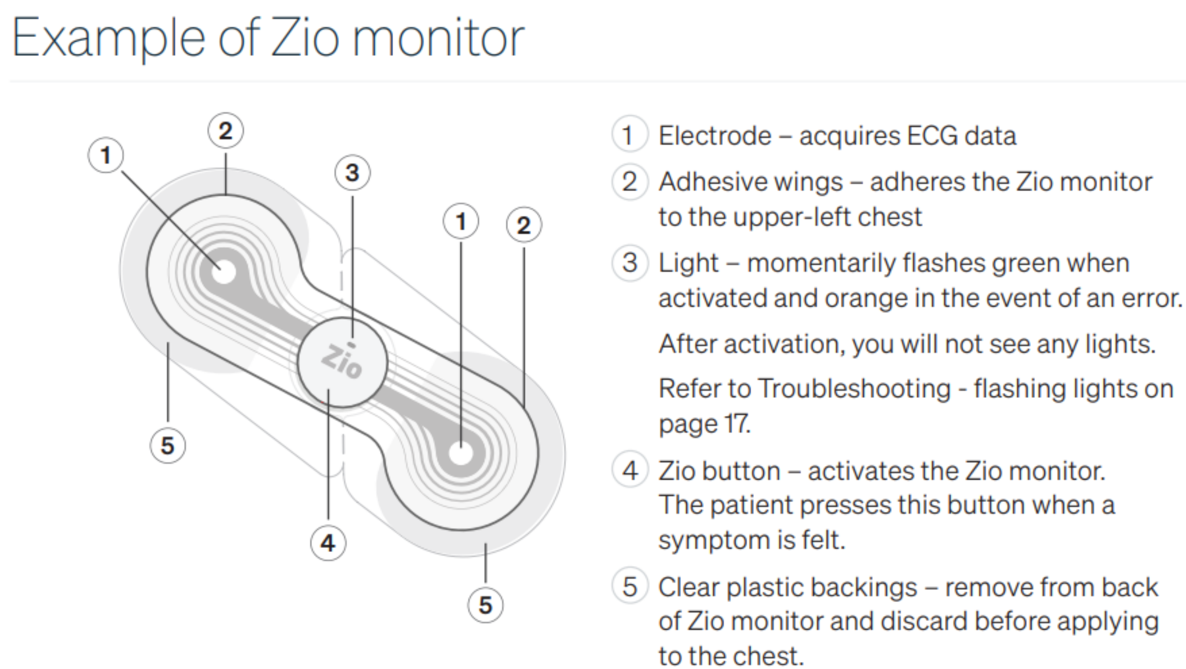
Claim 8	Accused Instrumentalities

	Multiple high-speed interfaces are supported including HS-USB, secure digital interface (SD, SDIO, MMC, SD-HC, and microSD™), SPI, UART, and I²C serial interfaces, and an audio subsystem supporting PDM, PCM, I²S, and TDM interfaces. An 8-input, 10-bit ADC is available to monitor analog inputs from external sensors and meters. The devices are available in 109-bump WLP (0.35mm pitch) and 121-bump CTBGA (0.65mm pitch).
	
	Applications
	• Connected Home
	• Industrial Sensors
	• Payment/Fitness/Medical Wearables
	• Telemedicine
	• Gaming Devices
	• Hearables
	
	(MAX32666 Datasheet)
	
	Benefits and Features
	• High-Efficiency Microcontroller and Audio DSP for Wearable and Hearable Devices
	  • Arm Cortex-M4 with FPU Up to 96MHz
	  • Optional Second Arm Cortex-M4 with FPU Optimized for Data Processing
	  • Low-Power, 7.3728MHz System Clock Option
	  • 1MB Flash, Organized into Dual Banks 2 x 512KB
	  • 560KB SRAM; 3 x 16KB Cache
	• Bluetooth 5 Low Energy Radio
	  • 1Mbps and 2Mbps Data Throughput
	  • Long Range (125kbps and 500kbps)
	  • Advertising Extension
	  • Rx Sensitivity: -95dbm; Tx Power Up to +4.5dbm
	  • On-Chip Matching with Single-Ended Antenna Port
	
	(MAX32666 Datasheet)

Claim 8	Accused Instrumentalities
	MAX32665/MAX32666 The MAX32665/MAX32666 are Arm Cortex-M4 with FPU-based microcontrollers with 1MB flash and 560KB SRAM. They are ideal for wearable medical fitness applications. A second Arm Cortex-M4 with FPU supporting ROM and cache supports extended data processing capabilities such as audio processing for wireless Bluetooth applications. The architecture includes a Bluetooth 5 Low Energy radio. The devices feature five powerful and flexible power modes. The flash memory is split into two banks of 512KB to provide flexibility when programming over the air. A built-in single inductor multiple output (SIMO) switch mode power supply allows the device to be optionally self-powered by a primary lithium cell. Dedicated hardware runs the Bluetooth 5 Low Energy stack freeing the CPUs for data processing tasks. Built-in dynamic clock gating and firmware-controlled power gating allow the user to optimize power for the specific application. Multiple SPI, UART, and I^2C serial interfaces, 1-Wire Master, and USB 2.0 High-Speed Device interface allow interconnection to a wide variety of external sensors. An audio subsystem supports PDM, PCM, I^2S, and TDM. An 8-input, 10-bit ADC is available to monitor analog input from external sensors and meters. The MAX32666 incorporates a trust protection unit (TPU) with encryption and advanced security features. These features include a modular arithmetic accelerator (MAA) for fast ECDSA, a hardware AES engine, a hardware TRNG entropy generator, a SHA-2 accelerator, and a secure bootloader. All devices are available in a 109-bump WLP with 0.35mm pitch and a 121-bump CTBGA with 0.65mm pitch packages. (MAX32666 Datasheet) **Arm Cortex-M4 with FPU Processor** The Arm Cortex-M4 with FPU processors CPU0 and CPU1 are ideal for the emerging category of wearable medical and wellness applications. The architecture combines high-efficiency signal processing functionality with low power, low cost, and ease of use. The Arm Cortex-M4 with FPU DSP supports single instruction multiple data (SIMD) path DSP extensions, providing: ● Four parallel 8-bit add/sub ● Floating point single precision ● Two parallel 16-bit add/sub ● Two parallel MACs ● 32- or 64-bit accumulate ● Signed, unsigned, data with or without saturation (MAX32666 Datasheet)

<table>
<tr><th><u>Claim 8</u></th><th><u>Accused Instrumentalities</u></th></tr>
<tr><td>8[h] wherein the first electrocardiographic electrode and the second electrocardiographic electrode are coupled to the flexible circuit,</td><td>

The Accused Instrumentalities include wherein the first electrocardiographic electrode and the second electrocardiographic electrode are coupled to the flexible circuit. The Zio Monitor satisfies 8[h] because the Zio Monitor has electrocardiographic electrodes that are coupled to the flexible circuit.



(https://go.irhythmtech.com/hubfs/LB10117.01%20-%20ZIO%20MONITOR%20INSTRUCTIONS%20FOR%20USE%2c%20PRINTED%20(2).pdf)

</td></tr>
</table>

Claim 8	Accused Instrumentalities
	 Zio Monitor (https://go.irhythmtech.com/hubfs/LB10117.01%20-%20ZIO%20MONITOR%20INSTRUCTIONS%20FOR%20USE%2c%20PRINTED%20(2).pdf) 

Claim 8	**Accused Instrumentalities**
	(Zio Monitor Teardown)  (Zio Monitor Teardown)

Claim 8	**Accused Instrumentalities**
	(Zio Monitor Teardown)

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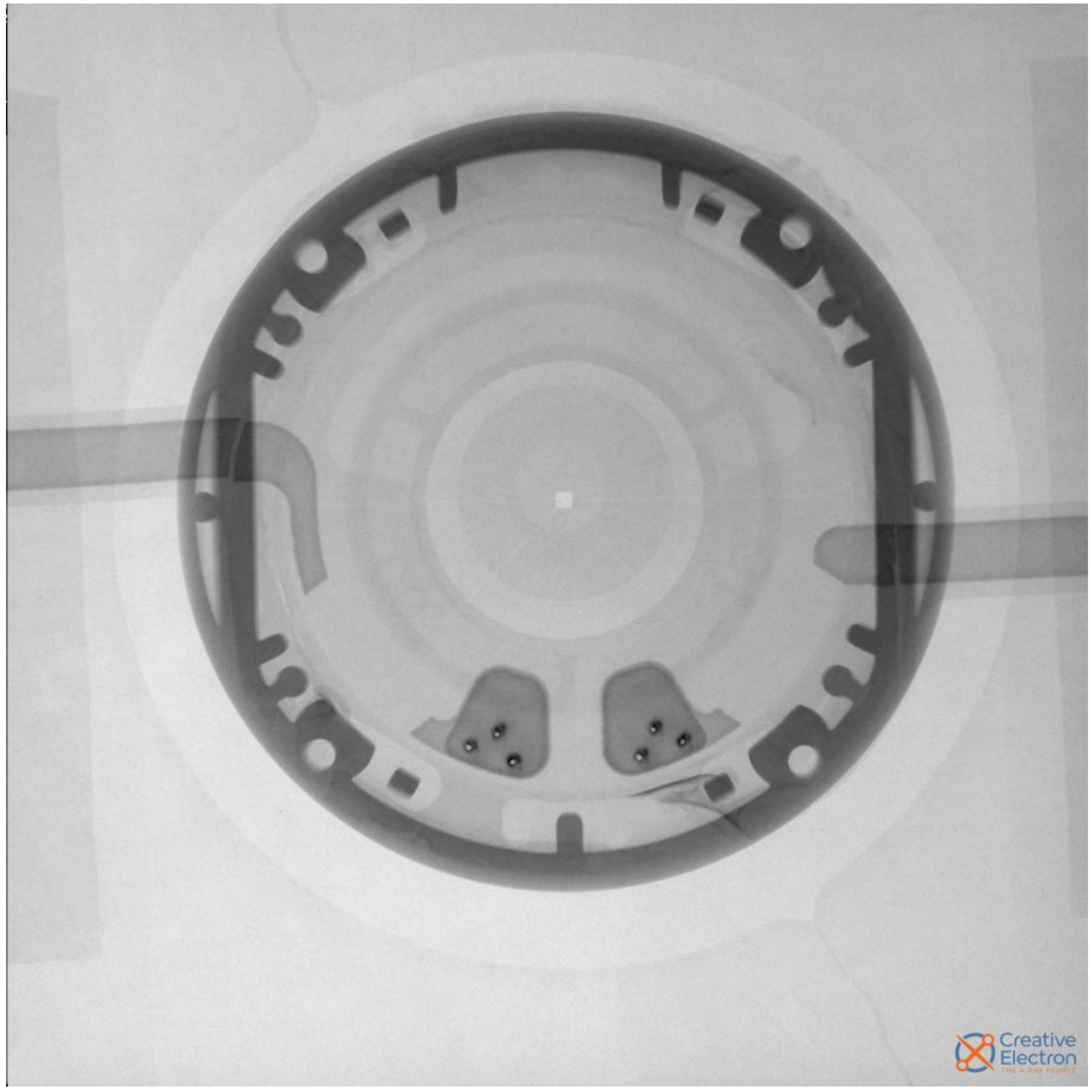
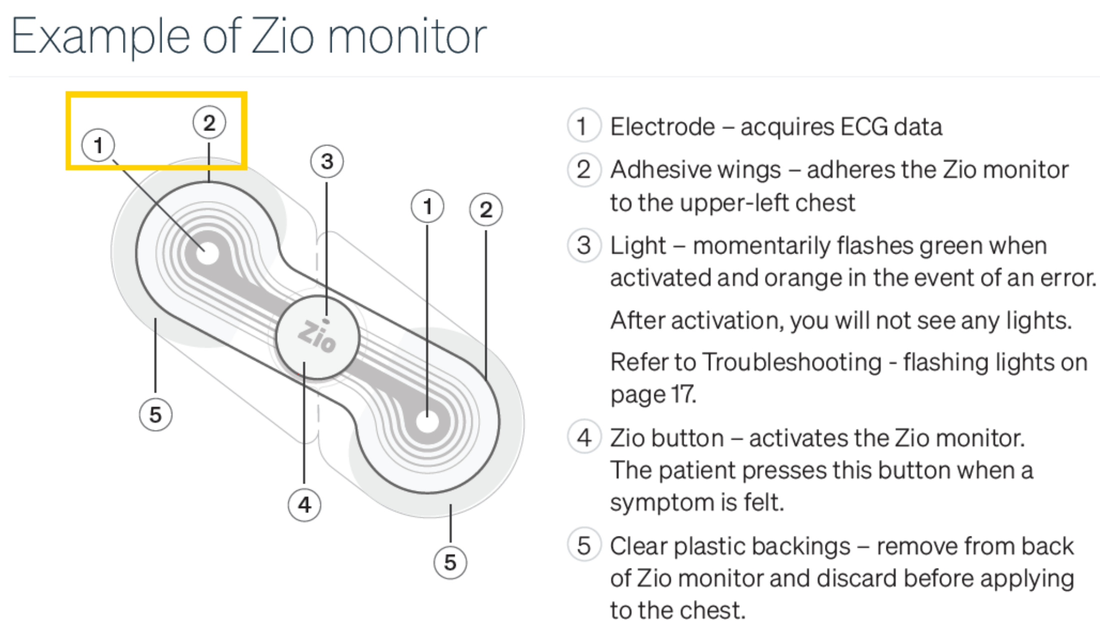
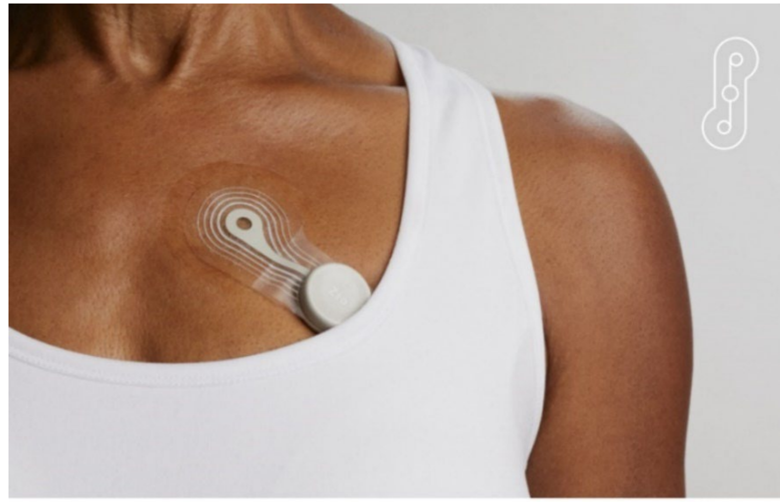
Claim 8	Accused Instrumentalities
	 (Zio Monitor Teardown)

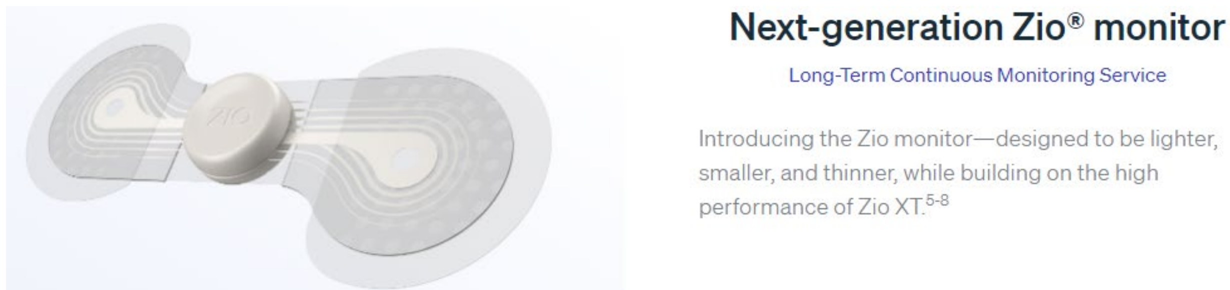
Claim 8	Accused Instrumentalities
	 (Zio Monitor Teardown)  (Zio Monitor Teardown)

321819903.2

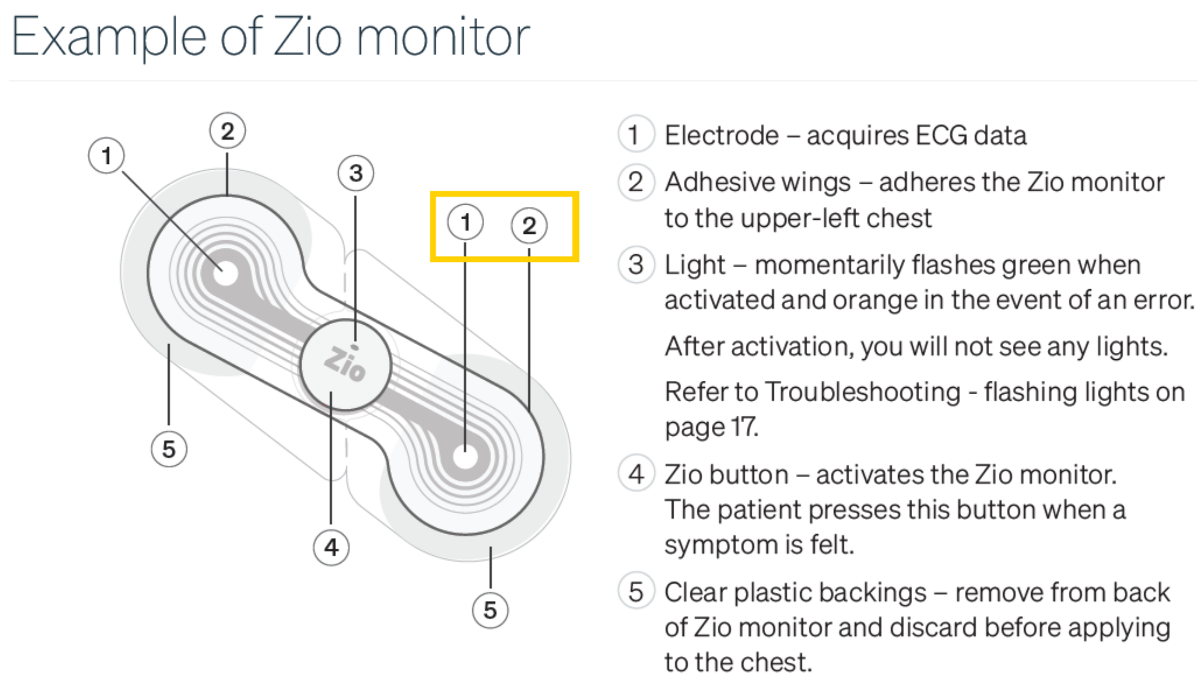
<table>
<tr><th><u>Claim 8</u></th><th><u>Accused Instrumentalities</u></th></tr>
<tr><td>8[i] wherein the first electrocardiographic electrode is conductively exposed at the first face along the first end section of the strip,</td><td>The Accused Instrumentalities include wherein the first electrocardiographic electrode is conductively exposed at the first face along the first end section of the strip. The Zio Monitor satisfies 8[i] because the Zio Monitor includes an electrocardiographic electrode conductively exposed on the upper side (i.e., the first face) along one end (i.e., the first end section) of the strip.


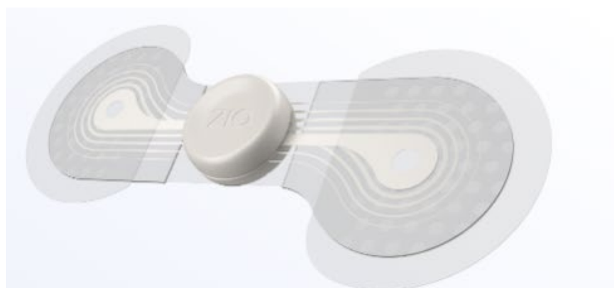
(https://go.irhythmtech.com/hubfs/LB10117.01%20-%20ZIO%20MONITOR%20INSTRUCTIONS%20FOR%20USE%2c%20PRINTED%20(2).pdf)</td></tr>
</table>

Claim 8	Accused Instrumentalities
	 Zio Monitor (https://go.irhythmtech.com/hubfs/LB10117.01%20-%20ZIO%20MONITOR%20INSTRUCTIONS%20FOR%20USE%2c%20PRINTED%20(2).pdf) The Zio patches include the following features: • patented flexible, lightweight, wire-free design; • unobtrusive and inconspicuous profile; • proprietary adhesive backing designed to keep the Zio patch securely in place for the duration of the prescribed wear period; (https://go.irhythmtech.com/hubfs/LB10117.01%20-%20ZIO%20MONITOR%20INSTRUCTIONS%20FOR%20USE%2c%20PRINTED%20(2).pdf)

<u>**Claim 8**</u>	<u>**Accused Instrumentalities**</u>
	 (https://www.irhythmtech.com/providers/zio-service/zio-monitors)  (https://vimeo.com/861741895?)

Claim 8	**Accused Instrumentalities**
	 (Zio Monitor Teardown)

Claim 8	Accused Instrumentalities
8[j] wherein the second electrocardiographic electrode is conductively exposed at the first face along the second end section of the strip,	***The Accused Instrumentalities include wherein the second electrocardiographic electrode is conductively exposed at the first face along the second end section of the strip.*** The Zio Monitor satisfies 8[j] because the Zio Monitor includes an electrocardiographic electrode conductively exposed on the upper side (*i.e.*, the first face) along one end (*i.e.*, the second end section) of the strip.  (https://go.irhythmtech.com/hubfs/LB10117.01%20-%20ZIO%20MONITOR%20INSTRUCTIONS%20FOR%20USE%2c%20PRINTED%20(2).pdf)

Claim 8	**Accused Instrumentalities**
	The Zio patches include the following features: • patented flexible, lightweight, wire-free design; • unobtrusive and inconspicuous profile; • proprietary adhesive backing designed to keep the Zio patch securely in place for the duration of the prescribed wear period; (https://go.irhythmtech.com/hubfs/LB10117.01%20-%20ZIO%20MONITOR%20INSTRUCTIONS%20FOR%20USE%2c%20PRINTED%20(2).pdf)  **Next-generation Zio® monitor** Long-Term Continuous Monitoring Service Introducing the Zio monitor—designed to be lighter, smaller, and thinner, while building on the high performance of Zio XT.[5-8] (https://www.irhythmtech.com/providers/zio-service/zio-monitors)

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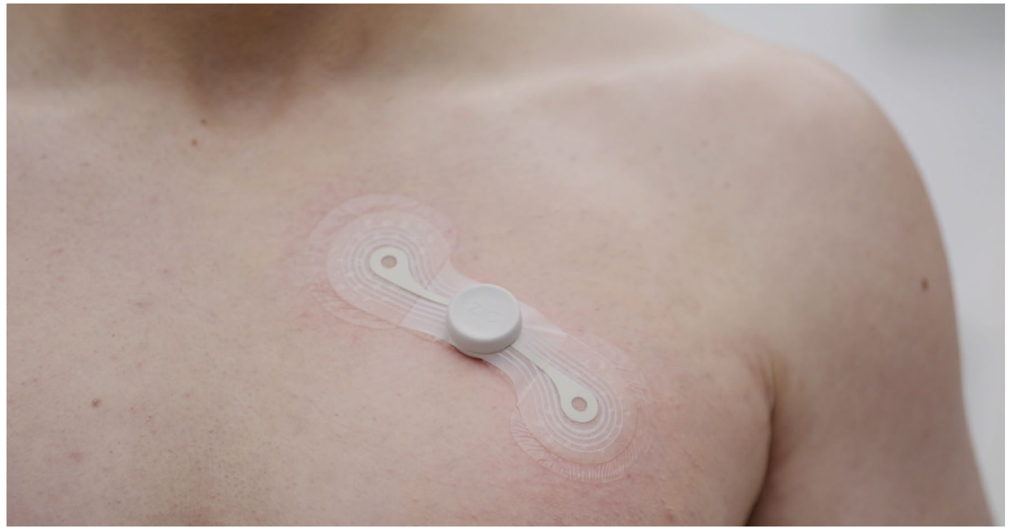
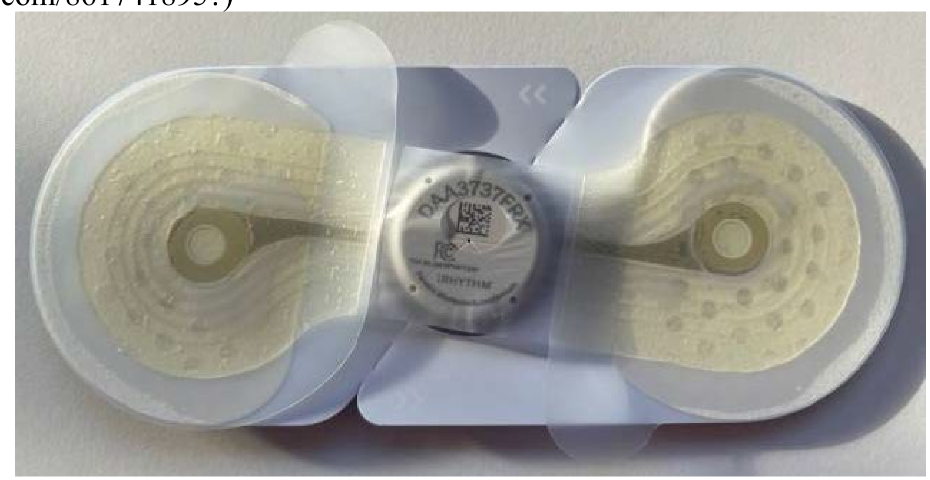
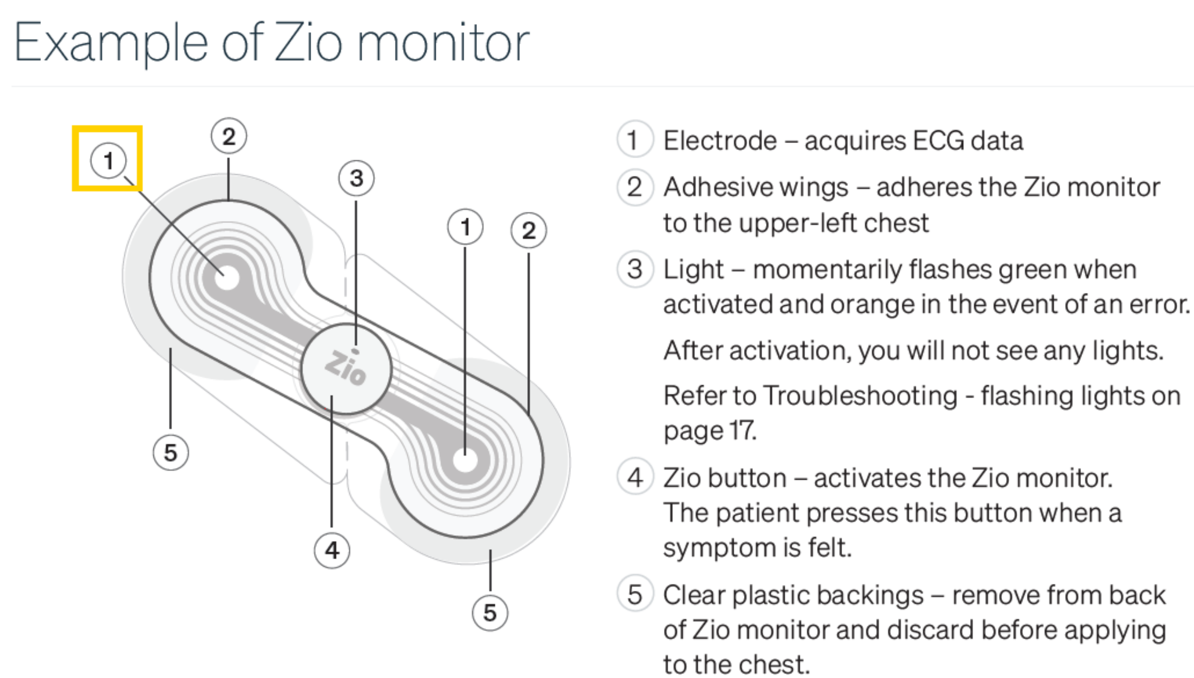
Claim 8	**Accused Instrumentalities**
	 (https://vimeo.com/861741895?)  (Zio Monitor Teardown)

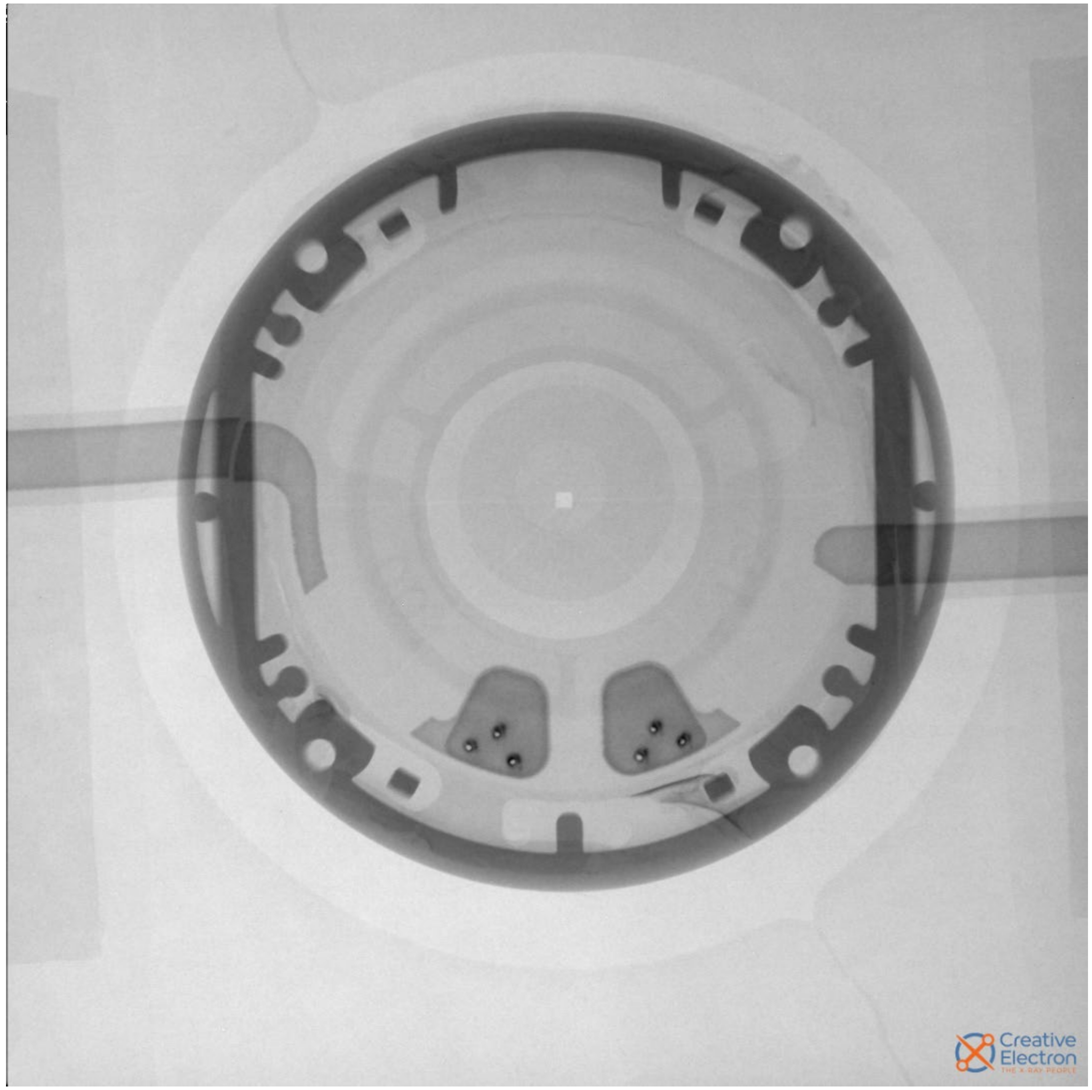
Claim 8	Accused Instrumentalities
8[k] wherein the first circuit trace is electrically coupled to the first electrocardiographic electrode, and	***The Accused Instrumentalities include wherein the first circuit trace is electrically coupled to the first electrocardiographic electrode.*** The Zio Monitor satisfies 8[k] because the Zio Monitor includes circuit traces, one of which is electrically coupled to one of the electrocardiographic electrodes (*i.e.*, the first electrocardiographic electrode).  (https://go.irhythmtech.com/hubfs/LB10117.01%20-%20ZIO%20MONITOR%20INSTRUCTIONS%20FOR%20USE%2c%20PRINTED%20(2).pdf)

Claim 8	**Accused Instrumentalities**
	 Zio Monitor (https://go.irhythmtech.com/hubfs/LB10117.01%20-%20ZIO%20MONITOR%20INSTRUCTIONS%20FOR%20USE%2c%20PRINTED%20(2).pdf)

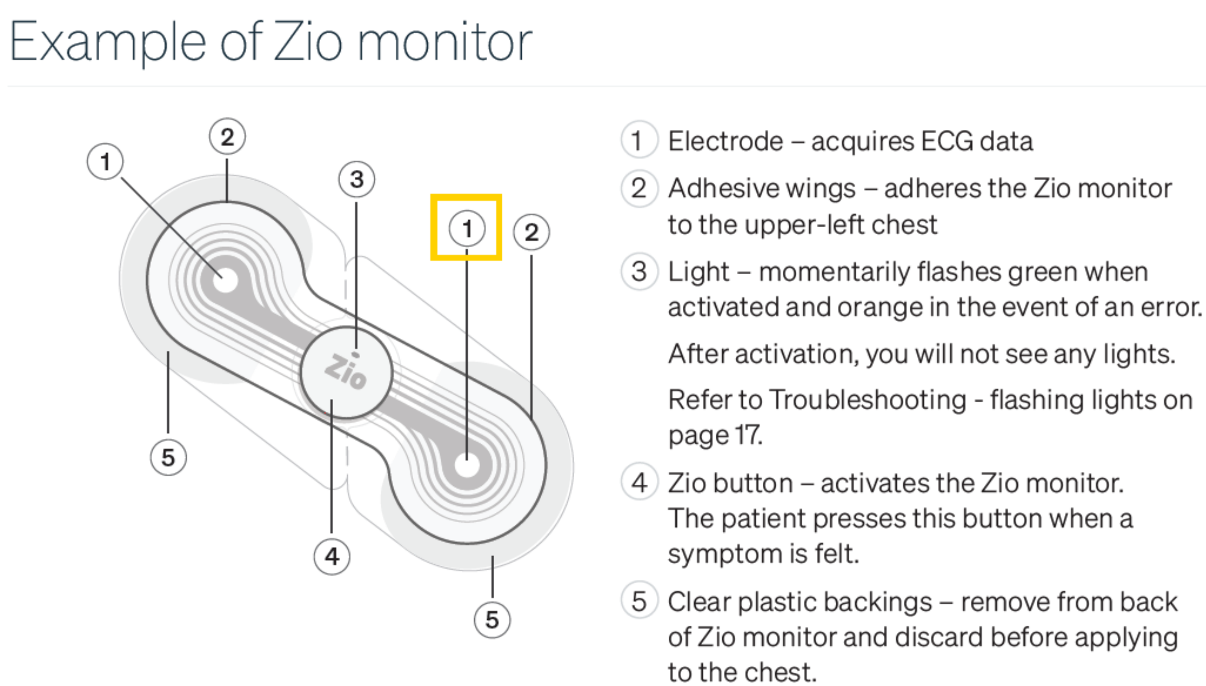
Claim 8	Accused Instrumentalities
	Day: From a technical viewpoint what we did was really to leverage a lot of advances not just in microprocessor efficiency, which is certainly part of it in terms of miniaturization as well as energy efficiency, but also we really challenged ourselves to figure out how to effectively fit in the smallest possible form factor, which for us was motivated a lot by the size of our battery, which is just a standard, easily available, and fortunately easily recyclable coin cell battery. We challenged ourselves to figure out how to miniaturize the device down to the level of one of those coin cells instead of the two that the Zio XT device uses. And that became feasible by the advances in microelectronic microprocessor efficiency and size as well through its miniaturization. But it also required a lot of really complicated dynamics from an electrical engineering perspective to figure out how to get all the components of a wearable medical device and a biosensor onto that small form factor. So, miniaturization was focused on very clever ways of handling some of the larger components, which for example involved moving some of the big resistors that are required on the device to the more flexible part of the patch instead of on the actual printed circuit board in the housing. And this is a patented feature that we've already received a patent on it and we're pursuing more around it, but it was the idea that these three big resistors are not too big in terms of the homage that they have but also in terms of the size that they are. So, if you put them on the circuit board, they are these pretty big components, so we realized pretty early on that we couldn't really do that and still fit the design constraints. So, we innovated a different way, which was to integrate it into the ECG tracings themselves. (https://www.mddionline.com/cardiovascular/behind-the-design-how-irhythm-built-its-new-zio-monitor)

Claim 8	**Accused Instrumentalities**
	 (Zio Monitor Teardown)  (Zio Monitor Teardown)

Claim 8	**Accused Instrumentalities**
	 (Zio Monitor Teardown)

Claim 8	Accused Instrumentalities
	 (Zio Monitor Teardown)

Claim 8	Accused Instrumentalities
	 (Zio Monitor Teardown)  (Zio Monitor Teardown)

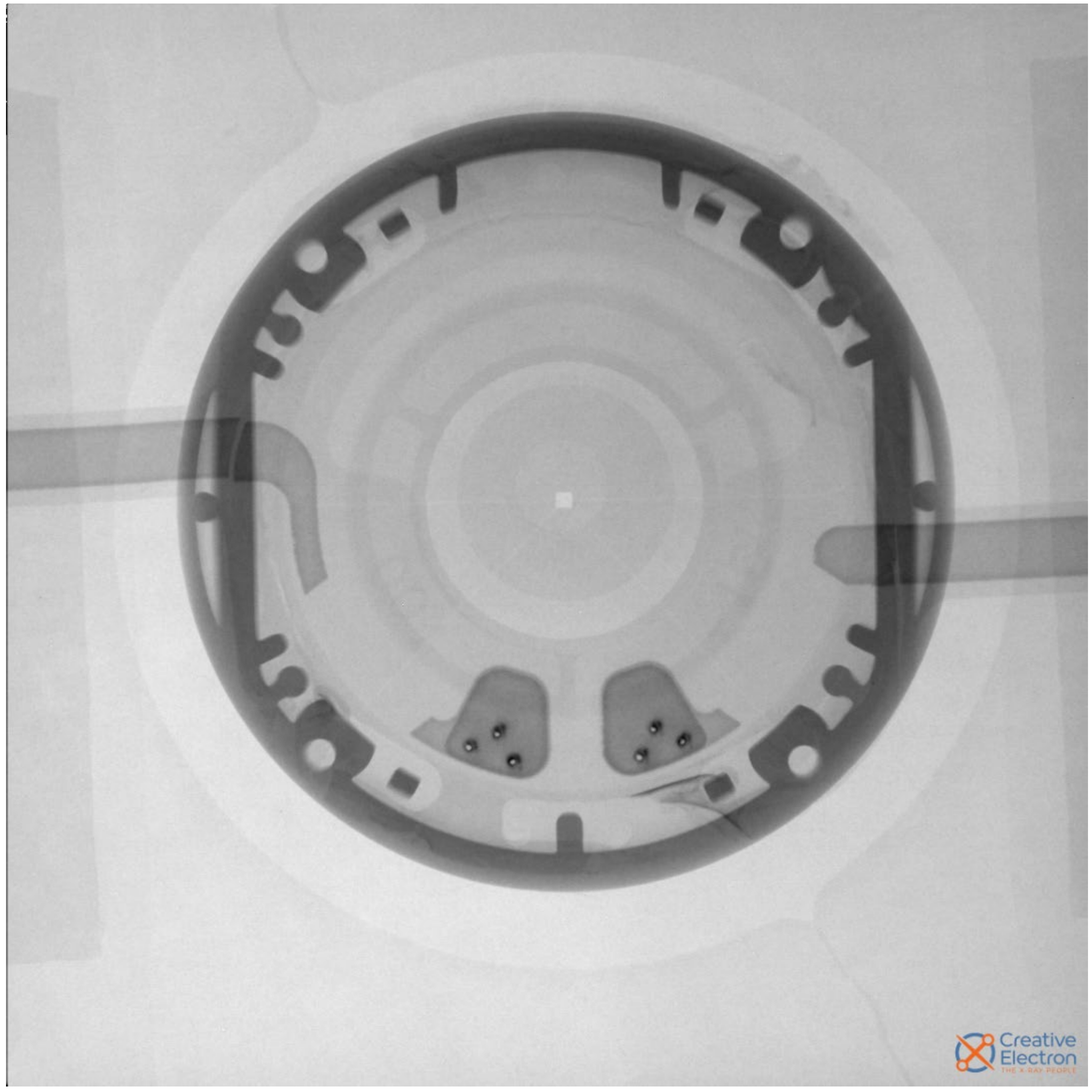
Claim 8	Accused Instrumentalities
8[l] wherein the second circuit trace is electrically coupled to the second electrocardiographic electrode;	***The Accused Instrumentalities include wherein the second circuit trace is electrically coupled to the second electrocardiographic electrode.*** The Zio Monitor satisfies 8[l] because the Zio Monitor includes circuit traces, one of which is coupled to one of the electrocardiographic electrodes (*i.e.*, the second electrocardiographic electrode).  (https://go.irhythmtech.com/hubfs/LB10117.01%20-%20ZIO%20MONITOR%20INSTRUCTIONS%20FOR%20USE%2c%20PRINTED%20(2).pdf)

<table>
<tr><th><u>Claim 8</u></th><th><u>Accused Instrumentalities</u></th></tr>
<tr><td></td><td>


(Zio Monitor Teardown)

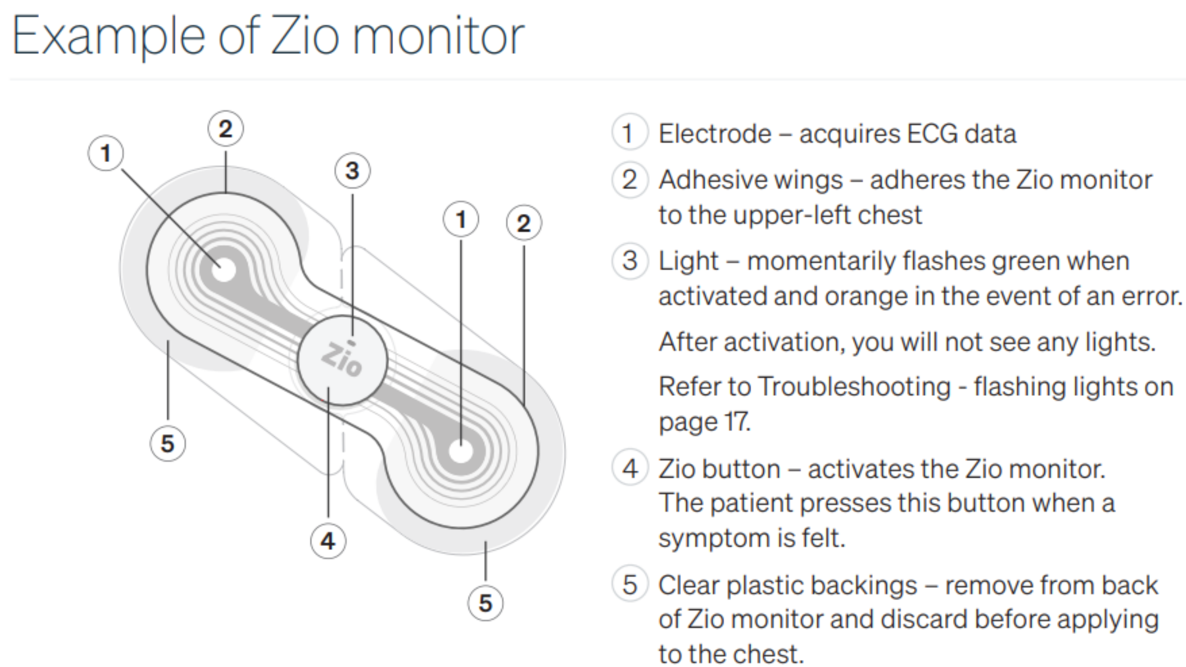
(Zio Monitor Teardown)
</td></tr>
</table>

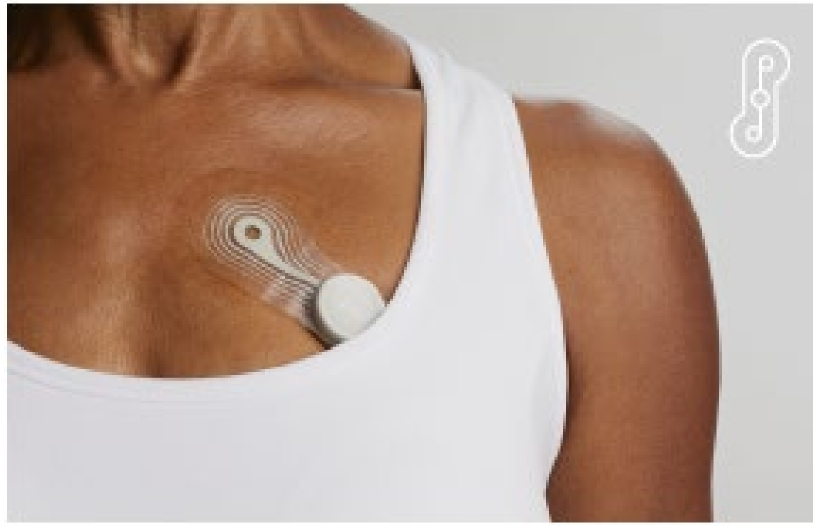
Claim 8	Accused Instrumentalities
	 (Zio Monitor Teardown)

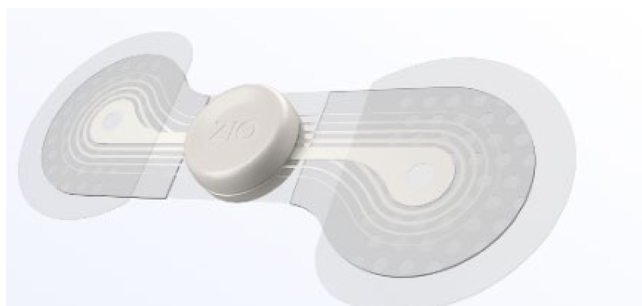
Claim 8	Accused Instrumentalities
	 (Zio Monitor Teardown)

Claim 8	Accused Instrumentalities
	 (Zio Monitor Teardown)  (Zio Monitor Teardown)

Claim 8	**Accused Instrumentalities**
	Day: From a technical viewpoint what we did was really to leverage a lot of advances not just in microprocessor efficiency, which is certainly part of it in terms of miniaturization as well as energy efficiency, but also we really challenged ourselves to figure out how to effectively fit in the smallest possible form factor, which for us was motivated a lot by the size of our battery, which is just a standard, easily available, and fortunately easily recyclable coin cell battery. We challenged ourselves to figure out how to miniaturize the device down to the level of one of those coin cells instead of the two that the Zio XT device uses. And that became feasible by the advances in microelectronic microprocessor efficiency and size as well through its miniaturization. But it also required a lot of really complicated dynamics from an electrical engineering perspective to figure out how to get all the components of a wearable medical device and a biosensor onto that small form factor. So, miniaturization was focused on very clever ways of handling some of the larger components, which for example involved moving some of the big resistors that are required on the device to the more flexible part of the patch instead of on the actual printed circuit board in the housing. And this is a patented feature that we've already received a patent on it and we're pursuing more around it, but it was the idea that these three big resistors are not too big in terms of the homage that they have but also in terms of the size that they are. So, if you put them on the circuit board, they are these pretty big components, so we realized pretty early on that we couldn't really do that and still fit the design constraints. So, we innovated a different way, which was to integrate it into the ECG tracings themselves. (https://www.mddionline.com/cardiovascular/behind-the-design-how-irhythm-built-its-new-zio-monitor)

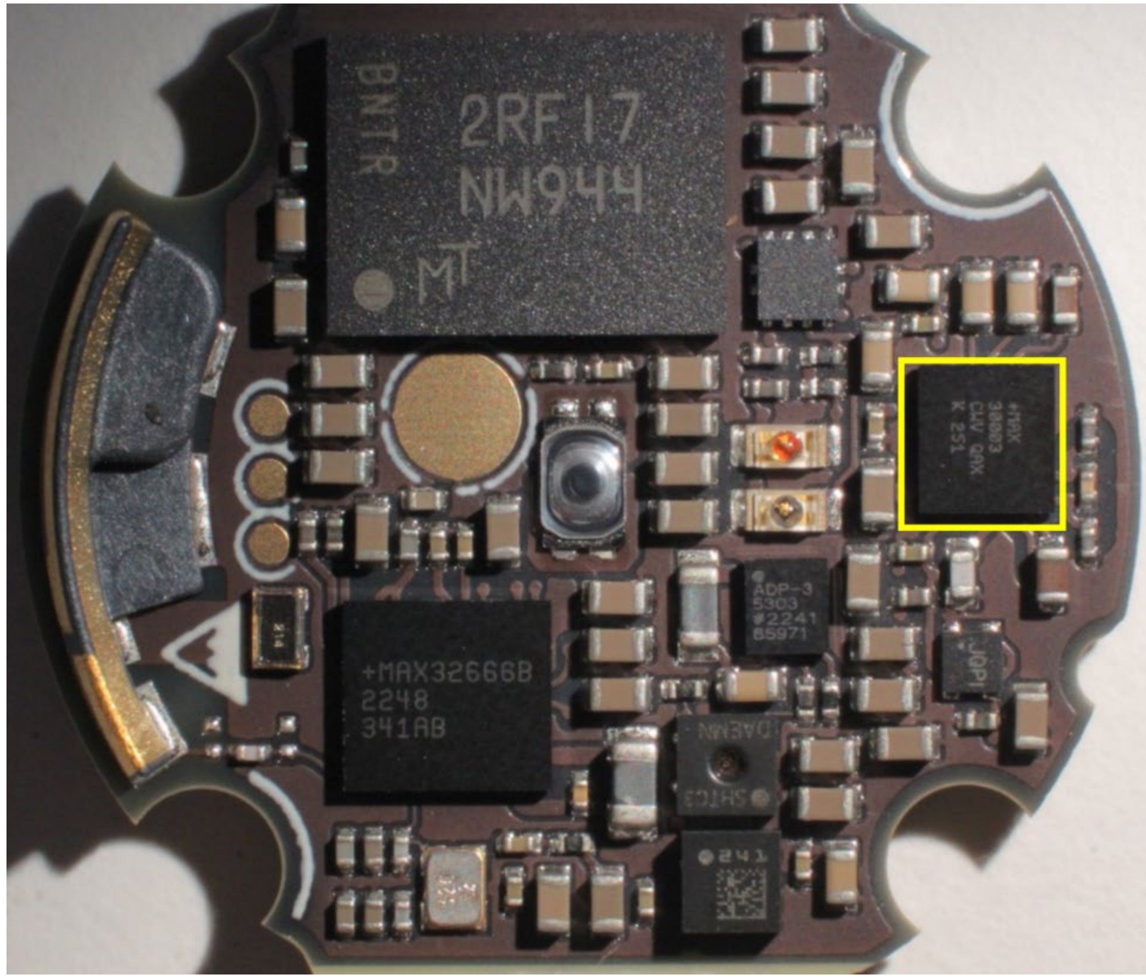
Claim 8	**Accused Instrumentalities**
8[m] wherein the first electrocardiographic electrode includes an inline resistor;	***The Accused Instrumentalities include wherein the first electrocardiographic electrode includes an inline resistor.*** The Zio Monitor satisfies 8[m] because the Zio Monitor includes an inline resistor.  (https://go.irhythmtech.com/hubfs/LB10117.01%20-%20ZIO%20MONITOR%20INSTRUCTIONS%20FOR%20USE%2c%20PRINTED%20(2).pdf)

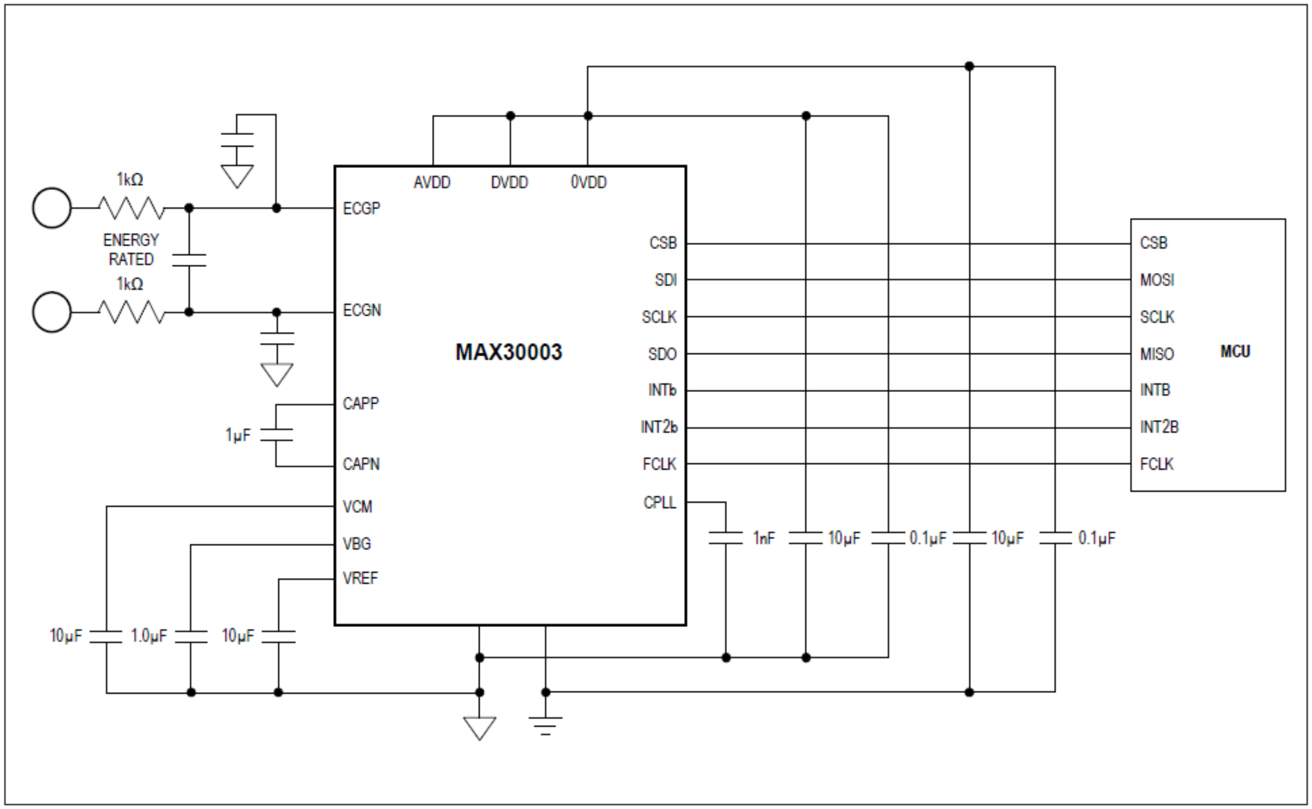
Claim 8	Accused Instrumentalities
	 Zio Monitor (https://go.irhythmtech.com/hubfs/LB10117.01%20-%20ZIO%20MONITOR%20INSTRUCTIONS%20FOR%20USE%2c%20PRINTED%20(2).pdf)

Claim 8	Accused Instrumentalities
	ZIO MONITOR SYSTEM The Zio Monitor System is the next generation of the Zio XT System, and is a prescription-only, remote ECG monitoring system that consists of the Zio Monitor patch that records the electric signal from the heart continuously for up to 14 days and the ZEUS System, which supports the capture and analysis of ECG data recorded by the Zio Monitor patch at the end of the wear period, including specific arrhythmia events detected by the ZEUS algorithm. (https://go.irhythmtech.com/hubfs/LB10117.01%20-%20ZIO%20MONITOR%20INSTRUCTIONS%20FOR%20USE%2c%20PRINTED%20(2).pdf)  **Next-generation Zio® monitor** Long-Term Continuous Monitoring Service Introducing the Zio monitor—designed to be lighter, smaller, and thinner, while building on the high performance of Zio XT.[5-8] (https://www.irhythmtech.com/providers/zio-service/zio-monitors)

Claim 8	Accused Instrumentalities
	 (Zio Monitor Teardown)  (Zio Monitor Teardown)

Claim 8	Accused Instrumentalities
	 (Zio Monitor Teardown)  (Zio Monitor Teardown)

Claim 8	Accused Instrumentalities
	 (Zio Monitor Teardown)

Claim 8	Accused Instrumentalities
	 (MAX30003 Datasheet)

Claim 8	Accused Instrumentalities
	ANALOG DEVICES Evaluation Kit Available · Design Resources · Tools and Models · Support *Click here to ask an associate for production status of specific part numbers.* **Ultra-Low Power, Single-Channel Integrated Biopotential (ECG, R-to-R Detection) AFE** **MAX30003** **General Description** The MAX30003 is a complete, biopotential, analog front-end solution for wearable applications. It offers high performance for clinical and fitness applications, with ultra-low power for long battery life. The MAX30003 is a single biopotential channel providing ECG waveforms and heart rate detection. The biopotential channel has ESD protection, EMI filtering, internal lead biasing, DC leads-off detection, ultra-low power leads-on detection during standby mode, and extensive calibration voltages for built-in self-test. Soft power-up sequencing ensures no large transients are injected into the electrodes. The biopotential channel also has high input impedance, low noise, high CMRR, programmable gain, various low-pass and high-pass filter options, and a high resolution analog-to-digital converter. The biopotential channel is DC coupled, can handle large electrode voltage offsets, and has a fast recovery mode to quickly recover from overdrive conditions, such as defibrillation and electrosurgery. The MAX30003 is available in a 28-pin TQFN and 30-bump wafer-level package (WLP), operating over the 0°C to +70°C commercial temperature range. (MAX30003 Datasheet)

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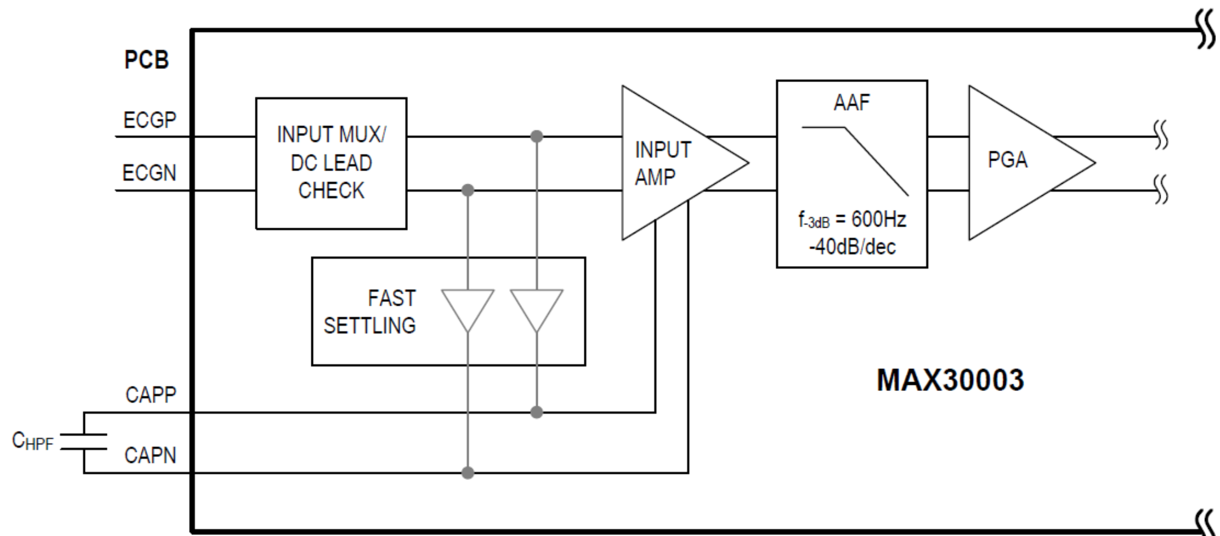
Claim 8	Accused Instrumentalities
	 (MAX30003 Datasheet)

Claim 8	Accused Instrumentalities
	Input MUX The ECG input MUX shown in Figure 3 contains integrated ESD and EMI protection, DC leads off detect current sources, lead-on detect, series isolation switches, lead biasing, and a programmable calibration voltage source to enable channel built in self-test. **EMI Filtering and ESD Protection** EMI filtering of the ECGP and ECGN inputs consists of a single pole, low pass, differential, and common mode filter with the pole located at approximately 2MHz. The ECGP and ECGN inputs also have input clamps that protect the inputs from ESD events. • ±8kV using the Contact Discharge method specified in IEC61000-4-2 ESD • ±15kV using the Air Gap Discharge method specified in IEC61000-4-2 ESD • ±8kV HBM • For IEC61000-4-2 ESD protection, use 1kΩ series resistors on ECGP and ECGN that is rated to withstand 8kV surge voltages. (MAX30003 Datasheet)

Claim 8	Accused Instrumentalities
	See figure and table below

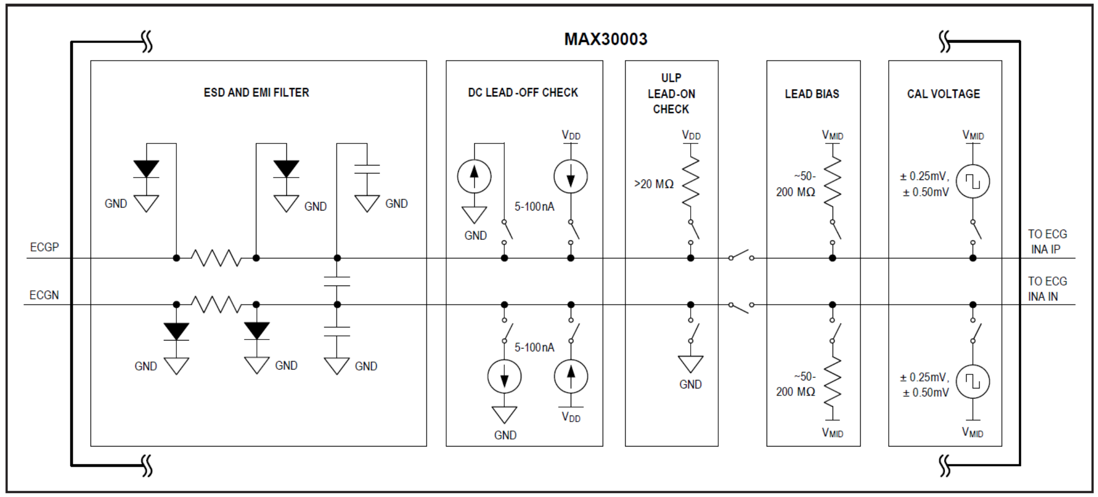


Figure 3. ECG Input MUX

(MAX30003 Datasheet)

Table 21. CNFG_GEN (0x10) Register Functionality (continued)

INDEX	NAME	DEFAULT	FUNCTION
D[3:2]	RBIASV[1:0]	01	Resistive Bias Mode Value Selection 00 = R_{BIAS} = 50MΩ 01 = R_{BIAS} = 100MΩ 10 = R_{BIAS} = 200MΩ 11 = Reserved. Do not use.
D[1]	RBIASP	0	Enables Resistive Bias on Positive Input 0 = ECGP is not resistively connected to V_{MID} 1 = ECGP is connected to V_{MID} through a resistor (selected by RBIASV).
D[0]	RBIASN	0	Enables Resistive Bias on Negative Input 0 = ECGN is not resistively connected to V_{MID} 1 = ECGN is connected to V_{MID} through a resistor (selected by RBIASV).

Table 22 shows the ECG data rates that can be realized with various setting of FMSTR, along with RATE configuration bits available in the CNFG_ECG register. Note FMSTR also determines the timing resolution of the CAL waveform generator.

(MAX30003 Datasheet)

Claim 8	Accused Instrumentalities
	Timing Characteristics (continued) (V_{DVDD} = V_{AVDD} = +1.1V to +2.0V, V_{OVDD} = +1.65V to +3.6V, T_A = T_{MIN} to T_{MAX}, unless otherwise noted. Typical values are at V_{DVDD} = +1.8V, V_{OVDD} = +2.5V, T_A = +25°C.) (Notes 2, 3) <table><tr><th>PARAMETER</th><th>SYMBOL</th><th>CONDITIONS</th><th>MIN</th><th>TYP</th><th>MAX</th><th>UNITS</th></tr><tr><td>CSB Fall to SDO Fall</td><td>t_{DOE}</td><td>Enable time, C_{LOAD} = 20pf</td><td></td><td></td><td>30</td><td>ns</td></tr><tr><td>CSB Rise to SDO Hi-Z</td><td>t_{DOZ}</td><td>Disable time</td><td></td><td></td><td>35</td><td>ns</td></tr><tr><td>FCLK Frequency</td><td>f_{FCLK}</td><td>External reference clock</td><td></td><td>32.768</td><td></td><td>kHz</td></tr><tr><td>FCLK Period</td><td>t_{FP}</td><td></td><td></td><td>30.52</td><td></td><td>µs</td></tr><tr><td>FCLK Pulse-Width High</td><td>t_{FH}</td><td>50% duty cycle assumed</td><td></td><td>15.26</td><td></td><td>µs</td></tr><tr><td>FCLK Pulse-Width Low</td><td>t_{FL}</td><td>50% duty cycle assumed</td><td></td><td>15.26</td><td></td><td>µs</td></tr></table> **Note 2:** Limits are 100% tested at T_A = +25°C. Limits over the operating temperature range and relevant supply voltage range are guaranteed by design and characterization. **Note 3:** Guaranteed by design and characterization. Not tested in production. **Note 4:** One electrode drive with <10Ω source impedance, the other driven with 51kΩ in parallel with a 47nF per IEC60601-2-47. **Note 5:** Inputs connected to 51kΩ in parallel with a 47nF to V_{CM}. **Note 6:** Use this setting only for V_{AVDD} = V_{DVDD} ≥ 1.65V. **Note 7:** Use this setting only for V_{AVDD} = V_{DVDD} ≥ 1.55V. **Note 8:** Use this setting only for V_{AVDD} = V_{DVDD} ≥ 1.45V. **Note 9:** This specification defines the accuracy of the calibration voltage source as applied to the ECG input, not as measured through the ADC channel. **Note 10:** f_{SCLK} = 4MHz, burst mode, EFIT = 8, C_{SDO} = C_{INTB} = 50pF. **Note 11:** ESD test performed with 1kΩ series resistor designed to withstand 8kV surge voltage. (MAX30003 Datasheet) But Mark Day, the chief technology officer at iRhythm, told *MD+DI* that the goal in designing the Zio monitor wasn't just to make it smaller, but to deliver a better patient wear experience. Below is a Q&A based on our conversation with Day, in which he explains why the company made these design changes, and how it accomplished it from an engineering perspective. The responses have been edited for length. (https://www.mddionline.com/cardiovascular/behind-the-design-how-irhythm-built-its-new-zio-monitor)

Claim 8	Accused Instrumentalities
	Day: From a technical viewpoint what we did was really to leverage a lot of advances not just in microprocessor efficiency, which is certainly part of it in terms of miniaturization as well as energy efficiency, but also we really challenged ourselves to figure out how to effectively fit in the smallest possible form factor, which for us was motivated a lot by the size of our battery, which is just a standard, easily available, and fortunately easily recyclable coin cell battery. We challenged ourselves to figure out how to miniaturize the device down to the level of one of those coin cells instead of the two that the Zio XT device uses. And that became feasible by the advances in microelectronic microprocessor efficiency and size as well through its miniaturization. But it also required a lot of really complicated dynamics from an electrical engineering perspective to figure out how to get all the components of a wearable medical device and a biosensor onto that small form factor. So, miniaturization was focused on very clever ways of handling some of the larger components, which for example involved moving some of the big resistors that are required on the device to the more flexible part of the patch instead of on the actual printed circuit board in the housing. And this is a patented feature that we've already received a patent on it and we're pursuing more around it, but it was the idea that these three big resistors are not too big in terms of the homage that they have but also in terms of the size that they are. So, if you put them on the circuit board, they are these pretty big components, so we realized pretty early on that we couldn't really do that and still fit the design constraints. So, we innovated a different way, which was to integrate it into the ECG tracings themselves. (https://www.mddionline.com/cardiovascular/behind-the-design-how-irhythm-built-its-new-zio-monitor)

Claim 8	**Accused Instrumentalities**
	(see below)

(12) **United States Patent**
Abercrombie, II et al.

(10) **Patent No.: US 11,399,760 B2**
(45) **Date of Patent: *Aug. 2, 2022**

(54) **WEARABLE DEVICE WITH CONDUCTIVE TRACES AND INSULATOR**

(71) Applicant: **iRhythm Technologies, Inc.**, San Francisco, CA (US)

(72) Inventors: **Jeffrey Joseph Abercrombie, II**, Oakland, CA (US); **Genaro Sebastian Sepulveda**, Oakland, CA (US); **Shena Hae Park**, San Francisco, CA (US); **Ryan James Wensley**, San Francisco, CA (US); **James Kihyun Lee**, San Francisco, CA (US); **Thomas Burnell Reeve, III**, San Francisco, CA (US)

(73) Assignee: **IRhythm Technologies, Inc.**, San Francisco, CA (US)

(*) Notice: Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 0 days.

This patent is subject to a terminal disclaimer.

(21) Appl. No.: **17/671,403**

(22) Filed: **Feb. 14, 2022**

(65) **Prior Publication Data**

US 2022/0160279 A1 May 26, 2022

Related U.S. Application Data

(63) Continuation of application No. 17/396,463, filed on Aug. 6, 2021, now Pat. No. 11,246,523.

(Continued)

(51) **Int. Cl.**
A61B 5/00 (2006.01)
A61B 5/257 (2021.01)
(Continued)

(52) **U.S. Cl.**
CPC *A61B 5/257* (2021.01); *A61B 5/282* (2021.01); *A61B 5/6833* (2013.01); *H05K 1/147* (2013.01);
(Continued)

(58) **Field of Classification Search**
CPC A61B 5/257; A61B 5/325; A61B 5/6833; A61B 5/6843; A61B 2090/0807;
(Continued)

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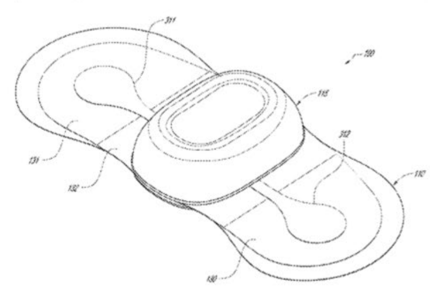
(Continued)

Primary Examiner — Eun Hwa Kim
Assistant Examiner — Adam Z Minchella
(74) *Attorney, Agent, or Firm* — Knobbe, Martens, Olson & Bear, LLP

(57) **ABSTRACT**

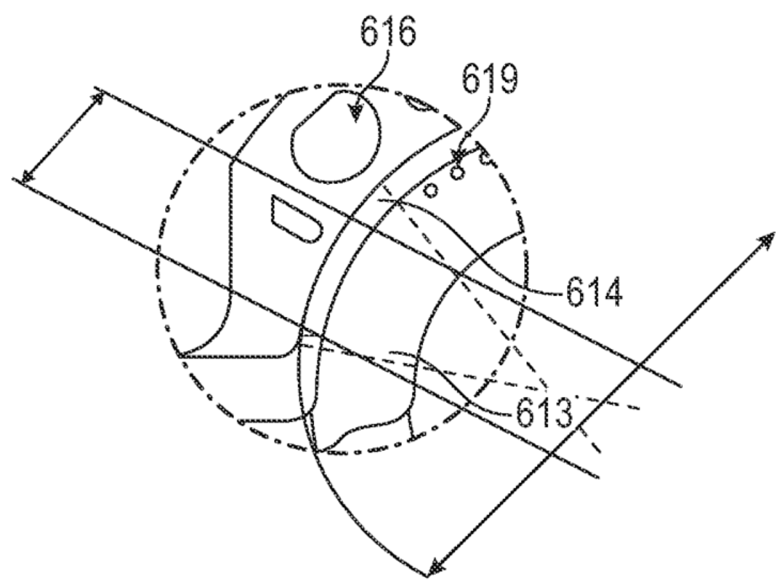
The present disclosure relates to a wearable device that includes a housing, battery terminal connector, conductive traces, and an insulator for recording signals. The device may include a housing enclosing a circuit board and a battery. The device may include two conductive traces electrically connected to terminals of the battery and an insulator separating the conductive traces. The battery terminal connector can present both the conductive traces to the outer surface for coupling to a circuit board. The device can assess the physiological signals to infer a likelihood of arrhythmia of a user.

30 Claims, 42 Drawing Sheets



(https://patentimages.storage.googleapis.com/12/7b/34/ee9a6b3db2a824/US11399760.pdf)

Claim 8	Accused Instrumentalities
	As shown in FIG. **10**B, in some embodiments, one or more resistors **614** may be disposed within the electrical traces **611**, **612**. The resistors **614** may comprise a conductive material of increased resistance over the conductive material(s) (e.g., silver and/or silver chloride) used to generally conduct electricity between the electrodes **350** and the PCBA **120**. For example, the resistors **614** may comprise carbon and/or increased amounts of carbon as compared to the electrical traces **611**, **612**. In some embodiments, the resistors may have a resistance that is at least approximately about: 50, 55, 60, 65, 70, 75, 80, 85, 90, 95, or 100 kiloohms (kΩ). The material of the resistor **614** may be selected to reduce or minimize "popcorn" noise or 1/f noise. As shown in FIGS. **10**A-**10**C, the resistors **614** may intersect the conductive path of the electrical traces **611**, **612** between the electrode interface portion **310** and the electrocardiogram interface portion **313** such that they are disposed in-line with the conductive material of the electrical traces **611**, **612**. The resistors **614** may be disposed on a housing portion of the trace layer **609** such that they are enclosed within the housing **115**. The resistors **614** may be disposed (e.g., printed) onto the substrate layer **613** in the same manner or a different manner from the conductive material of the electrical traces **611**, **612**. The resistors **614** may replace resistors that would otherwise be disposed on the PCBA **120**, thereby potentially providing space-saving advantages. In some embodiments, the resistors **614** may be used to reduce the current that travels along the electrical circuit formed by the body and the interfacing electrodes **350**. The resistors **614** may act as a safety feature that allows the physiological monitoring device **100** to be suitable for use with a patient.

Claim 8	Accused Instrumentalities
	(https://patentimages.storage.googleapis.com/12/7b/34/ee9a6b3db2a824/US11399760.pdf)  FIG. 10B (https://patentimages.storage.googleapis.com/12/7b/34/ee9a6b3db2a824/US11399760.pdf)

Claim 8	**Accused Instrumentalities**
	This web page is provided to satisfy the virtual patent marking provisions of various jurisdictions including the virtual patent marking provisions of the America Invents Act and provide notice under 35 U.S.C. §287(a), that the iRhythm Technologies' Zio patch products and related services, including but not limited to the Zio patch, Zio XT, Zio AT, and Zio MCT trademarked products, are covered by or for use under one or more of the patents listed below. Zio patch products and related services are covered by or for use under one or more international patents or international patent applications. Zio patch products and related services not listed here may be protected by one or more patents in the United States and other international jurisdictions and may be covered by patents in the United States and other international jurisdictions that are not listed. iRhythm Technologies' Zio patch products and related services may be sold individually or as part of a combination product or system. US Patent Numbers*: 8,538,503; 8,560,046; 9,173,670; 9,241,649; 9,451,975; 9,597,004; 9,955,887; 10,098,559; 10,271,754; 10,299,691; D852965; D854167; 10,405,799; 10,517,500; 11,141,091; 10,555,683; 11,627,902; 11,051,738; 10,667,712; 10,813,565; 11,605,458; 11,289,197; 11,350,864; 11,350,865; 11,589,792; 11,337,632; 11,504,041; 11,246,523; 11,399,760; 11,246,524; 11,382,555; 11,083,371; 11,253,185; 11,253,186; 11,375,941 and 11,497,432. Additional patents are pending in the United States. (https://www.irhythmtech.com/content/patents-trademarks)

Claim 8	Accused Instrumentalities
8[n] a battery;	***The Accused Instrumentalities include a battery.*** The Zio Monitor satisfies 8[n] because the Zio Monitor includes a battery. The battery powers the body worn device. **Power specifications** Battery type: 1 lithium manganese dioxide coin cell Battery life: > 14 days (https://go.irhythmtech.com/hubfs/LB10117.01%20-%20ZIO%20MONITOR%20INSTRUCTIONS%20FOR%20USE%2c%20PRINTED%20(2).pdf) **Precautions** • During storage and prior to prescription for a patient, do not exceed the temperature and humidity limitations for the Zio monitor. Devices exposed to environmental conditions outside the specified range may have degraded adhesive and battery performance. • Observe the temperature and humidity specifications for transportation and storage listed on the box and in the instructions for use. • Confirm the expiration date for the Zio monitor listed on the Zio box or pouch. Use of an expired device may cause a degradation of ECG signal quality and a low battery condition. Apply the device on or before expiration date. (https://go.irhythmtech.com/hubfs/LB10117.01%20-%20ZIO%20MONITOR%20INSTRUCTIONS%20FOR%20USE%2c%20PRINTED%20(2).pdf)

Claim 8	Accused Instrumentalities
	The Zio patches include the following features: • patented flexible, lightweight, wire-free design; • unobtrusive and inconspicuous profile; • proprietary adhesive backing designed to keep the Zio patch securely in place for the duration of the prescribed wear period; • water-resistant functionality, allowing patients to shower, sleep, and perform normal daily activities, including moderate exercise; • hydrogel electrodes and a compliant mechanical design to deliver a clear ECG with minimal artifact from movement; • large symptom button, or patient trigger, that is easy to find and press; • indicated single application wear period of up to 14 days (for longer prescribed wear periods for MCT services, additional Zio AT patches and gateways will be provided); and • sufficient battery power for the entire wear period, without the need to recharge or replace batteries. (https://go.irhythmtech.com/hubfs/LB10117.01%20-%20ZIO%20MONITOR%20INSTRUCTIONS%20FOR%20USE%2c%20PRINTED%20(2).pdf)

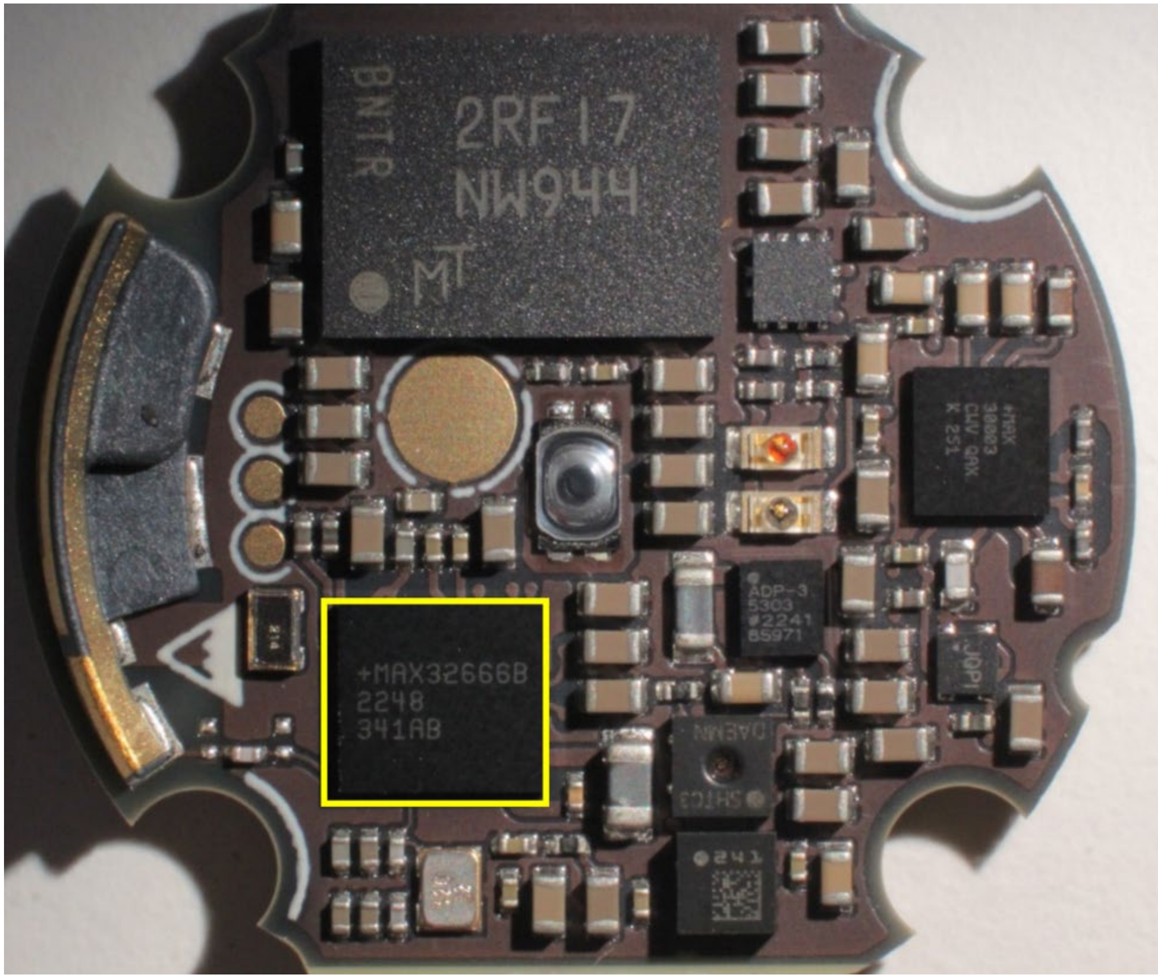
Claim 8	**Accused Instrumentalities**
	The Zio Monitor, our newest model, is 72% smaller and 62% lighter relative to the previous generation. The Zio Monitor uses 1 coin-cell battery, as compared to the 2 used in Zio XT. This is the second-most environmentally impactful component of our devices (after the circuit board). While we recycle these batteries, this is still a meaningful reduction in impact. (https://go.irhythmtech.com/hubfs/LB10117.01%20-%20ZIO%20MONITOR%20INSTRUCTIONS%20FOR%20USE%2c%20PRINTED%20(2).pdf) **ZIO MONITOR SYSTEM** The Zio Monitor System is the next generation of the Zio XT System, and is a prescription-only, remote ECG monitoring system that consists of the Zio Monitor patch that records the electric signal from the heart continuously for up to 14 days and the ZEUS System, which supports the capture and analysis of ECG data recorded by the Zio Monitor patch at the end of the wear period, including specific arrhythmia events detected by the ZEUS algorithm. (https://go.irhythmtech.com/hubfs/LB10117.01%20-%20ZIO%20MONITOR%20INSTRUCTIONS%20FOR%20USE%2c%20PRINTED%20(2).pdf)

Claim 8	Accused Instrumentalities
	 (Zio Monitor Teardown)  (Zio Monitor Teardown)

Claim 8	Accused Instrumentalities
	 (Zio Monitor Teardown)  (Zio Monitor Teardown)

321819903.2

Claim 8	Accused Instrumentalities
8[o] a wireless transceiver;	***The Accused Instrumentalities include a wireless transceiver.*** The Zio Monitor satisfies 8[o] because the Zio Monitor includes a wireless transceiver.  (Zio Monitor Teardown)

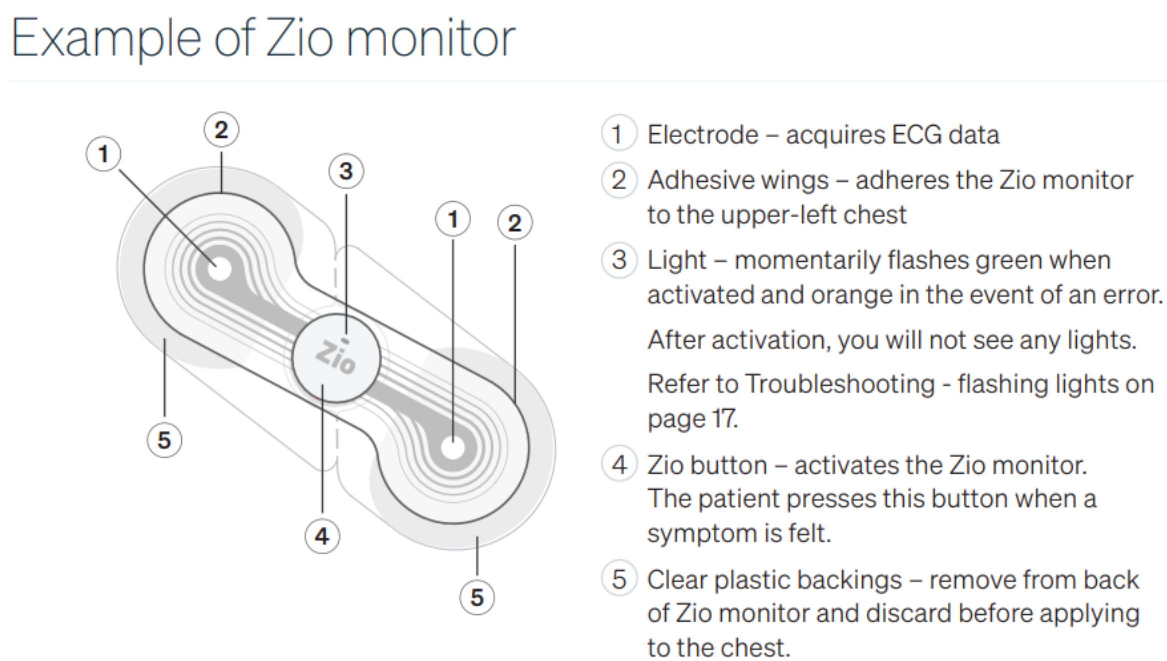
Claim 8	Accused Instrumentalities
	 (Zio Monitor Teardown)

Claim 8	**Accused Instrumentalities**
	ANALOG DEVICES Click here to ask an associate for production status of specific part numbers. MAX32665/MAX32666 Low-Power Arm Cortex-M4 with FPU-Based Microcontroller with Bluetooth 5 for Wearables **General Description** DARWIN is a new breed of low-power microcontrollers built to thrive in the rapidly evolving Internet of Things (IoT). They are smart, with the biggest memories in their class and a massively scalable memory architecture. They run forever, thanks to wearable-grade power technology. They are durable enough to withstand the most advanced cyberattacks. DARWIN microcontrollers are designed to run any application imaginable—in places where you would not dream of sending other microcontrollers. Generation UB microcontrollers are designed to handle the increasingly complex applications demanded by today's advanced battery-powered devices and wirelessly connected devices, while providing robust hardware security and Bluetooth® 5 Low Energy (Bluetooth LE) radio connectivity. The MAX32665/MAX32666 UB class microcontrollers are advanced systems-on-chips featuring an Arm® Cortex®-M4 with FPU CPU for efficient computation of complex functions and algorithms with integrated power management. It also includes the newest generation Bluetooth 5 LE radio with support for long range (4x) and high throughput (2Mbps) and ADI's best-in-class hardware security suite trust protection unit (TPU). The devices offer large on-board memory with 1MB flash and 560KB SRAM. Split flash banks of 512KB each support seamless over-the-air upgrades, adding an additional degree of reliability. Memory scalability of data (SRAM) and code (Flash) space is supported by two SPI execute-in-place (SPIX) interfaces. (MAX32666 Datasheet)

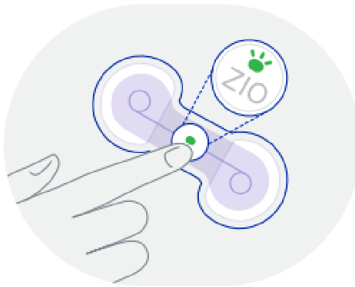
Claim 8	Accused Instrumentalities

	Multiple high-speed interfaces are supported including HS-USB, secure digital interface (SD, SDIO, MMC, SD-HC, and microSD™), SPI, UART, and I^2C serial interfaces, and an audio subsystem supporting PDM, PCM, I^2S, and TDM interfaces. An 8-input, 10-bit ADC is available to monitor analog inputs from external sensors and meters. The devices are available in 109-bump WLP (0.35mm pitch) and 121-bump CTBGA (0.65mm pitch).
	
	Applications
	• Connected Home
	• Industrial Sensors
	• Payment/Fitness/Medical Wearables
	• Telemedicine
	• Gaming Devices
	• Hearables
	
	(MAX32666 Datasheet)
	
	Benefits and Features
	• High-Efficiency Microcontroller and Audio DSP for Wearable and Hearable Devices
	  • Arm Cortex-M4 with FPU Up to 96MHz
	  • Optional Second Arm Cortex-M4 with FPU Optimized for Data Processing
	  • Low-Power, 7.3728MHz System Clock Option
	  • 1MB Flash, Organized into Dual Banks 2 x 512KB
	  • 560KB SRAM; 3 x 16KB Cache
	• Bluetooth 5 Low Energy Radio
	  • 1Mbps and 2Mbps Data Throughput
	  • Long Range (125kbps and 500kbps)
	  • Advertising Extension
	  • Rx Sensitivity: -95dbm; Tx Power Up to +4.5dbm
	  • On-Chip Matching with Single-Ended Antenna Port
	
	(MAX32666 Datasheet)

Claim 8	Accused Instrumentalities
	MAX32665/MAX32666 The MAX32665/MAX32666 are Arm Cortex-M4 with FPU-based microcontrollers with 1MB flash and 560KB SRAM. They are ideal for wearable medical fitness applications. A second Arm Cortex-M4 with FPU supporting ROM and cache supports extended data processing capabilities such as audio processing for wireless Bluetooth applications. The architecture includes a Bluetooth 5 Low Energy radio. The devices feature five powerful and flexible power modes. The flash memory is split into two banks of 512KB to provide flexibility when programming over the air. A built-in single inductor multiple output (SIMO) switch mode power supply allows the device to be optionally self-powered by a primary lithium cell. Dedicated hardware runs the Bluetooth 5 Low Energy stack freeing the CPUs for data processing tasks. Built-in dynamic clock gating and firmware-controlled power gating allow the user to optimize power for the specific application. Multiple SPI, UART, and I^2C serial interfaces, 1-Wire Master, and USB 2.0 High-Speed Device interface allow interconnection to a wide variety of external sensors. An audio subsystem supports PDM, PCM, I^2S, and TDM. An 8-input, 10-bit ADC is available to monitor analog input from external sensors and meters. The MAX32666 incorporates a trust protection unit (TPU) with encryption and advanced security features. These features include a modular arithmetic accelerator (MAA) for fast ECDSA, a hardware AES engine, a hardware TRNG entropy generator, a SHA-2 accelerator, and a secure bootloader. All devices are available in a 109-bump WLP with 0.35mm pitch and a 121-bump CTBGA with 0.65mm pitch packages. (MAX32666 Datasheet) **Arm Cortex-M4 with FPU Processor** The Arm Cortex-M4 with FPU processors CPU0 and CPU1 are ideal for the emerging category of wearable medical and wellness applications. The architecture combines high-efficiency signal processing functionality with low power, low cost, and ease of use. The Arm Cortex-M4 with FPU DSP supports single instruction multiple data (SIMD) path DSP extensions, providing: • Four parallel 8-bit add/sub • Floating point single precision • Two parallel 16-bit add/sub • Two parallel MACs • 32- or 64-bit accumulate • Signed, unsigned, data with or without saturation (MAX32666 Datasheet)

Claim 8	Accused Instrumentalities
8[p] a button configured to be pressed to mark an event;	***The Accused Instrumentalities include a button configured to be pressed to mark an event.*** The Zio Monitor satisfies 8[p] because the Zio Monitor includes a button configured to be pressed by a patient when a symptom (*i.e.*, an event) occurs.  (https://go.irhythmtech.com/hubfs/LB10117.01%20-%20ZIO%20MONITOR%20INSTRUCTIONS%20FOR%20USE%2c%20PRINTED%20(2).pdf)

Claim 8	Accused Instrumentalities
	The Zio monitor is a single-use ECG monitor that provides a continuous, single-channel recording for up to 14 days. The Zio monitor records ECG data without patient interaction, with the goal of improving patient compliance via simplicity of operation. Patients have the option of pressing a convenient button and filling out a log to document symptomatic events, which will support symptom-rhythm correlation in the diagnostic report. (https://go.irhythmtech.com/hubfs/LB10117.01%20-%20ZIO%20MONITOR%20INSTRUCTIONS%20FOR%20USE%2c%20PRINTED%20(2).pdf) A "symptom" is anything unusual the patient feels or experiences. **1. Press the button on your Zio monitor when you feel a symptom.** • The light does not flash when the button is pressed. • If you forget to either press the button or log a symptom, the Zio monitor is recording the ECG data. (https://go.irhythmtech.com/hubfs/LB10117.01%20-%20ZIO%20MONITOR%20INSTRUCTIONS%20FOR%20USE%2c%20PRINTED%20(2).pdf)

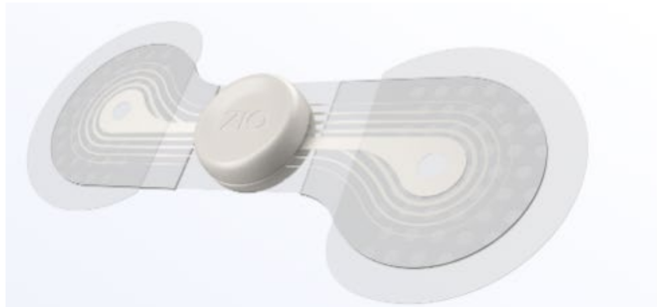
Claim 8	**Accused Instrumentalities**
	4. Activate Zio monitor  • **Press and release button:** a. Press and quickly release the button on the Zio monitor. b. Watch the light briefly flash green to indicate the Zio monitor is recording ECG data. (https://go.irhythmtech.com/hubfs/LB10117.01%20-%20ZIO%20MONITOR%20INSTRUCTIONS%20FOR%20USE%2c%20PRINTED%20(2).pdf)

Claim 8	Accused Instrumentalities
	The Zio patches include the following features: • patented flexible, lightweight, wire-free design; • unobtrusive and inconspicuous profile; • proprietary adhesive backing designed to keep the Zio patch securely in place for the duration of the prescribed wear period; • water-resistant functionality, allowing patients to shower, sleep, and perform normal daily activities, including moderate exercise; • hydrogel electrodes and a compliant mechanical design to deliver a clear ECG with minimal artifact from movement; • large symptom button, or patient trigger, that is easy to find and press; • indicated single application wear period of up to 14 days (for longer prescribed wear periods for MCT services, additional Zio AT patches and gateways will be provided); and • sufficient battery power for the entire wear period, without the need to recharge or replace batteries. (https://go.irhythmtech.com/hubfs/LB10117.01%20-%20ZIO%20MONITOR%20INSTRUCTIONS%20FOR%20USE%2c%20PRINTED%20(2).pdf)

Claim 8	Accused Instrumentalities
	 (Zio Monitor Teardown)  (Zio Monitor Teardown)

Claim 8	**Accused Instrumentalities**
	 (https://vimeo.com/861741895?)

Claim 8	Accused Instrumentalities
8[q] a sealed housing having rounded edges on a top surface,	***The Accused Instrumentalities include a sealed housing having rounded edges on a top surface.*** The Zio Monitor satisfies 8[q] because the Zio Monitor includes a sealed housing with rounded edges on its top surface.  Zio Monitor (https://go.irhythmtech.com/hubfs/LB10117.01%20-%20ZIO%20MONITOR%20INSTRUCTIONS%20FOR%20USE%2c%20PRINTED%20(2).pdf)

Claim 8	**Accused Instrumentalities**
	 **Next-generation Zio® monitor** Long-Term Continuous Monitoring Service Introducing the Zio monitor—designed to be lighter, smaller, and thinner, while building on the high performance of Zio XT.[5-8] (https://www.irhythmtech.com/providers/zio-service/zio-monitors) • **Other features that make it easy to wear and allow patients to go about their daily lives**[8] – it is breathable, has a hydrocolloid adhesive and a waterproof housing[9,10], and requires no device or adhesive manipulation or battery change during the entire wear and monitoring period of up to 14 days. (https://www.globenewswire.com/news-release/2023/09/26/2749471/0/en/iRhythm-Launches-Next-Generation-Zio-Monitor-and-Enhanced-Zio-Service-Its-Smallest-Lightest-and-Thinnest-Cardiac-Monitor.html)

Claim 8	Accused Instrumentalities
	 (Zio Monitor Teardown)  (Zio Monitor Teardown)

<u>Claim 8</u>	**<u>Accused Instrumentalities</u>**
8[r] wherein the sealed housing is coupled to the flexible backing, and	***The Accused Instrumentalities include a sealed housing wherein the sealed housing is coupled to the flexible backing.*** The Zio Monitor satisfies 8[r] because the Zio Monitor includes a sealed housing that is coupled to the flexible backing.  Zio Monitor (https://go.irhythmtech.com/hubfs/LB10117.01%20-%20ZIO%20MONITOR%20INSTRUCTIONS%20FOR%20USE%2c%20PRINTED%20(2).pdf)

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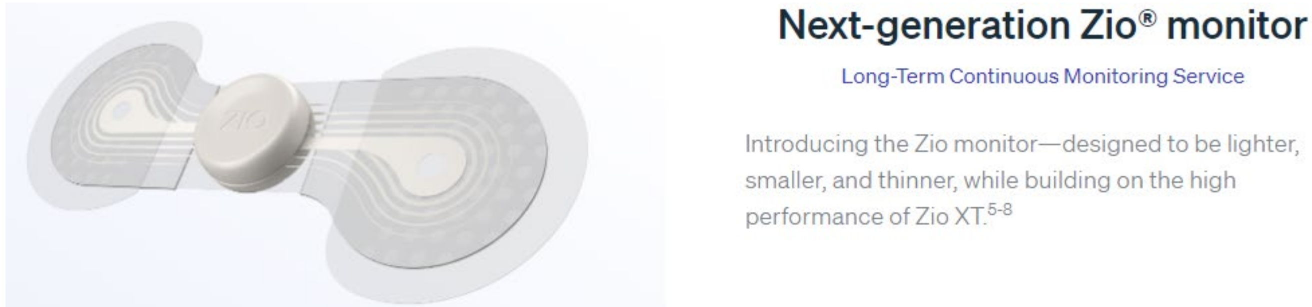
Claim 8	Accused Instrumentalities
	 (https://www.irhythmtech.com/providers/zio-service/zio-monitors)  (Zio Monitor Teardown)

Claim 8	**Accused Instrumentalities**
	 (Zio Monitor Teardown)

Claim 8	Accused Instrumentalities
8[s] wherein the sealed housing includes a processor,	***The Accused Instrumentalities include a sealed housing wherein the sealed housing includes a processor.*** The Zio Monitor satisfies 8[s] because the Zio Monitor has a processer in its sealed housing. Day: From a technical viewpoint what we did was really to leverage a lot of advances not just in microprocessor efficiency, which is certainly part of it in terms of miniaturization as well as energy efficiency, but also we really challenged ourselves to figure out how to effectively fit in the smallest possible form factor, which for us was motivated a lot by the size of our battery, which is just a standard, easily available, and fortunately easily recyclable coin cell battery. We challenged ourselves to figure out how to miniaturize the device down to the level of one of those coin cells instead of the two that the Zio XT device uses. And that became feasible by the advances in microelectronic microprocessor efficiency and size as well through its miniaturization. But it also required a lot of really complicated dynamics from an electrical engineering perspective to figure out how to get all the components of a wearable medical device and a biosensor onto that small form factor. So, (https://www.mddionline.com/cardiovascular/behind-the-design-how-irhythm-built-its-new-zio-monitor)

Claim 8	**Accused Instrumentalities**
	 (Zio Monitor Teardown)  (Zio Monitor Teardown)

Claim 8	Accused Instrumentalities
	 (Zio Monitor Teardown)  (Zio Monitor Teardown)

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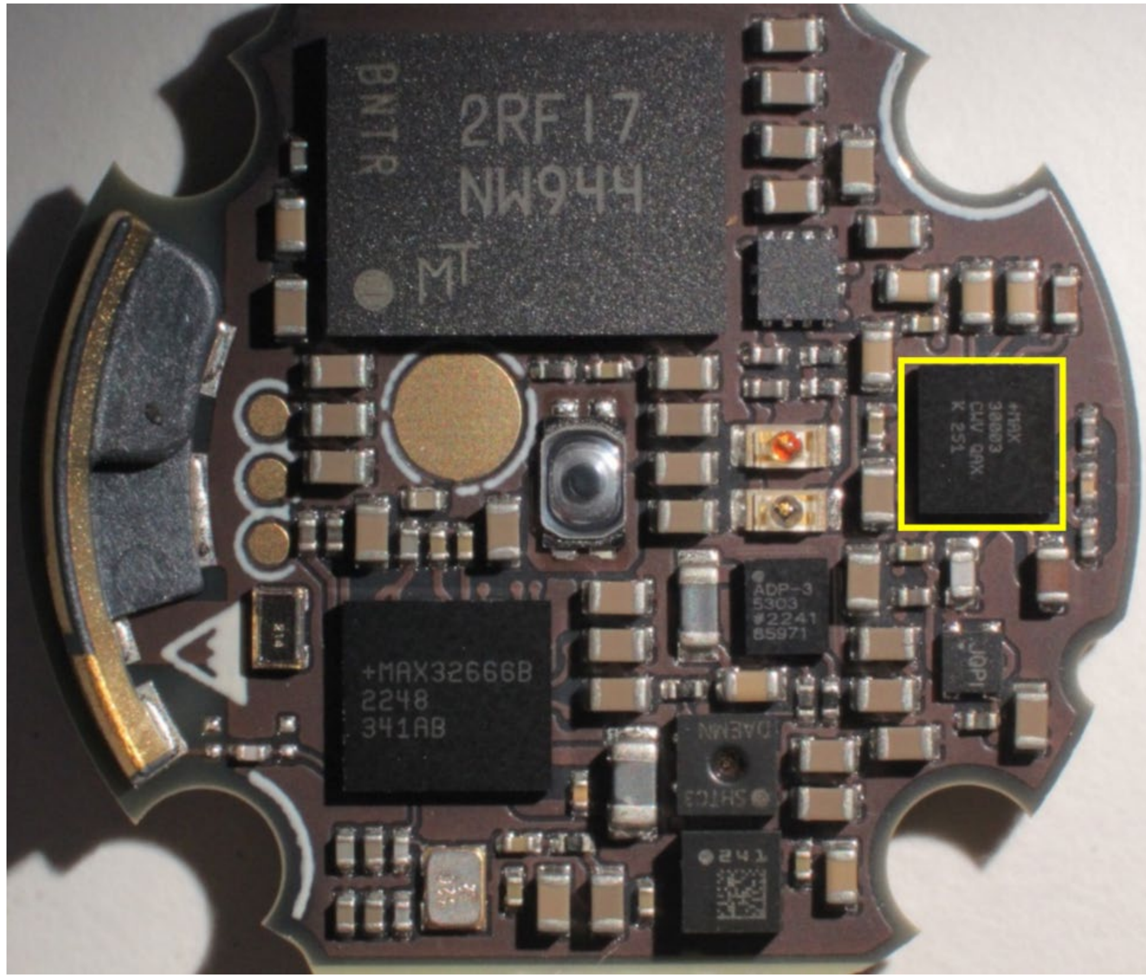
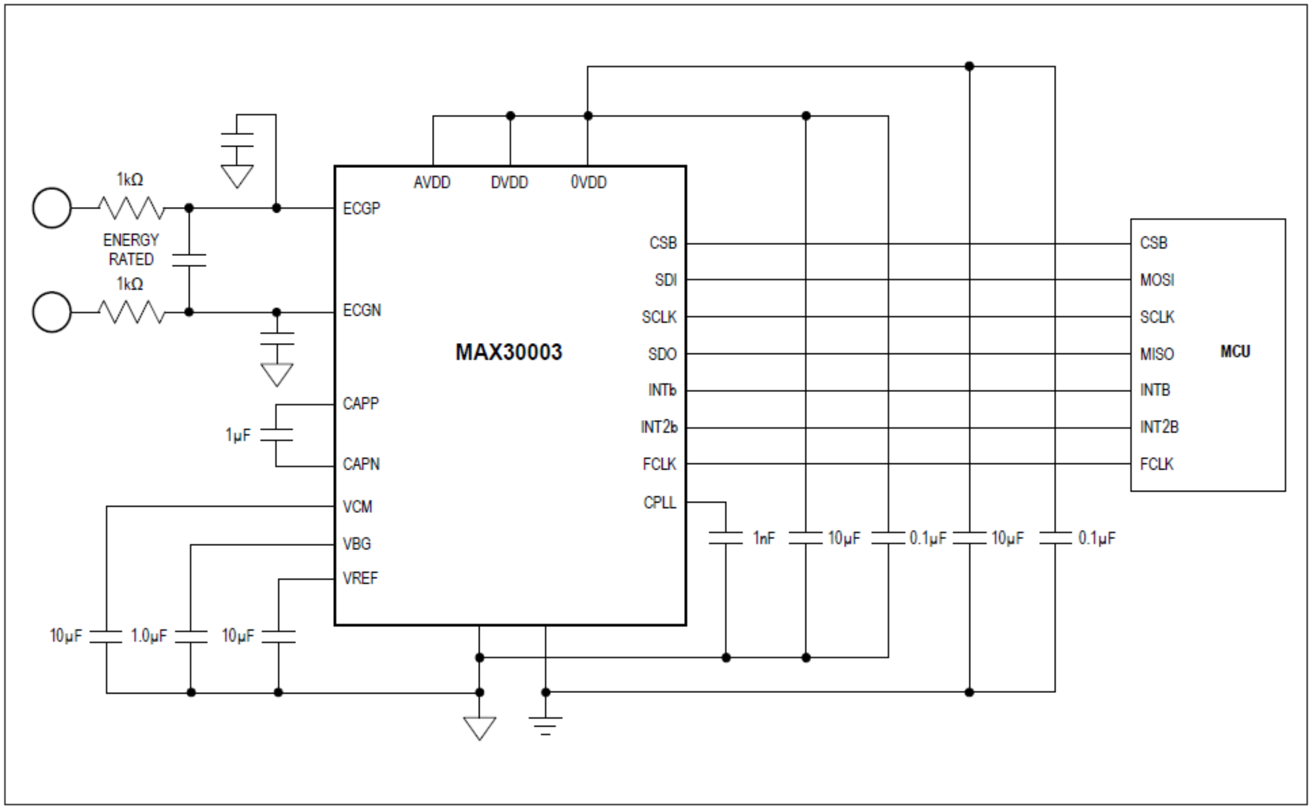
Claim 8	**Accused Instrumentalities**
	 (Zio Monitor Teardown)

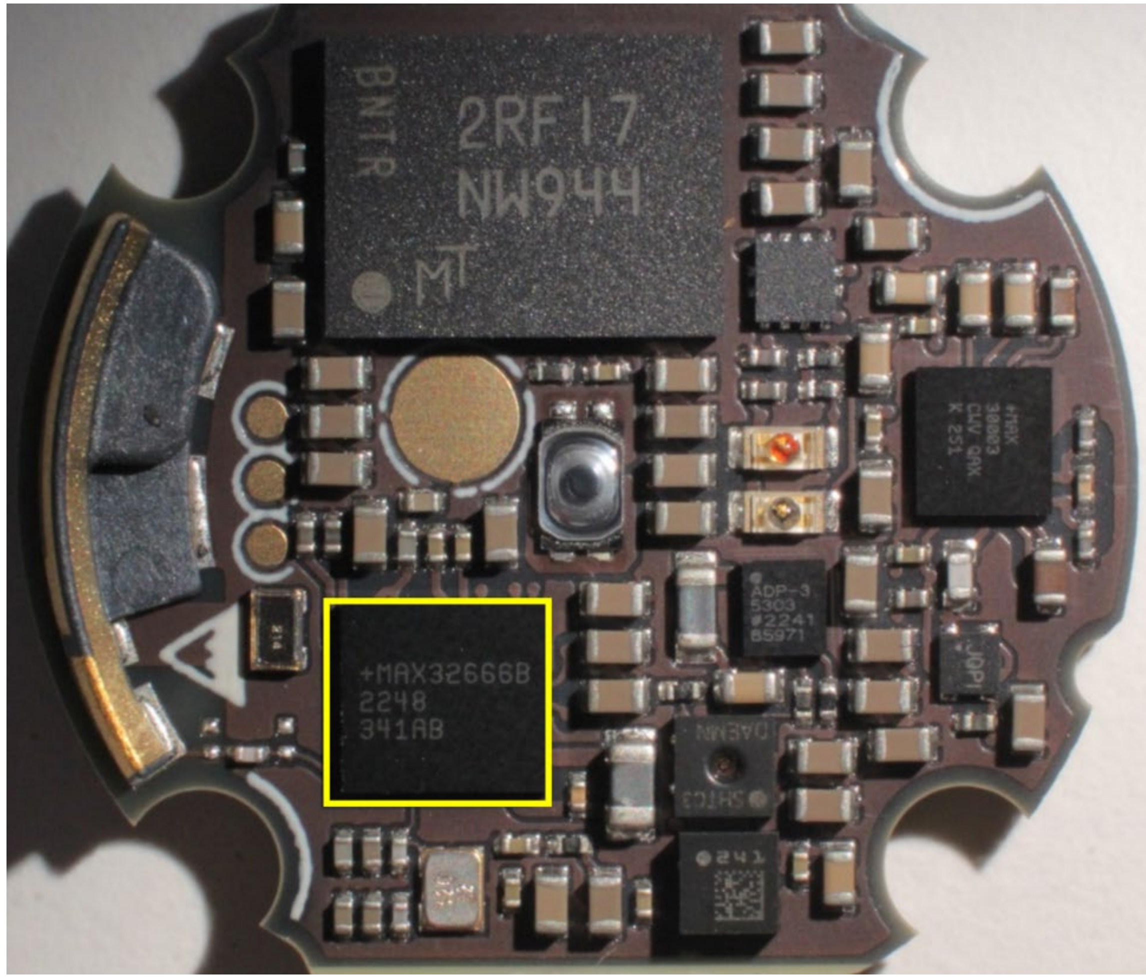
Claim 8	Accused Instrumentalities
	 (MAX30003 Datasheet)

Claim 8	Accused Instrumentalities
	ANALOG DEVICES Evaluation Kit Available · Design Resources · Tools and Models · Support *Click here to ask an associate for production status of specific part numbers.* **Ultra-Low Power, Single-Channel Integrated Biopotential (ECG, R-to-R Detection) AFE** **MAX30003** **General Description** The MAX30003 is a complete, biopotential, analog front-end solution for wearable applications. It offers high performance for clinical and fitness applications, with ultra-low power for long battery life. The MAX30003 is a single biopotential channel providing ECG waveforms and heart rate detection. The biopotential channel has ESD protection, EMI filtering, internal lead biasing, DC leads-off detection, ultra-low power leads-on detection during standby mode, and extensive calibration voltages for built-in self-test. Soft power-up sequencing ensures no large transients are injected into the electrodes. The biopotential channel also has high input impedance, low noise, high CMRR, programmable gain, various low-pass and high-pass filter options, and a high resolution analog-to-digital converter. The biopotential channel is DC coupled, can handle large electrode voltage offsets, and has a fast recovery mode to quickly recover from overdrive conditions, such as defibrillation and electrosurgery. The MAX30003 is available in a 28-pin TQFN and 30-bump wafer-level package (WLP), operating over the 0°C to +70°C commercial temperature range. (MAX30003 Datasheet)

Claim 8	Accused Instrumentalities

	Benefits and Features
	• Clinical-Grade ECG AFE with High-Resolution Data Converter
	  • 15.5 Bits Effective Resolution with 5µV_{P-P} Noise
	• Better Dry Starts Due to Much Improved Real World CMRR and High Input Impedance
	  • Fully Differential Input Structure with CMRR > 100dB
	• Offers Better Common-Mode to Differential Mode Conversion Due to High Input Impedance
	  • High Input Impedance > 500MΩ for Extremely Low Common-to-Differential Mode Conversion
	• Minimum Signal Attenuation at the Input During Dry Start Due to High Electrode Impedance
	• High DC Offset Range of ±650mV (1.8V, typ) Allows to Be Used with Wide Variety of Electrodes
	• High AC Dynamic Range of 65mV_{P-P} Will Help the AFE Not Saturate in the Presence of Motion/Direct Electrode Hits
	• Longer Battery Life Compared to Competing Solutions
	  • 85µW at 1.1V Supply Voltage
	• Leads-On Interrupt Feature Allows to Keep µC in Deep Sleep Mode with RTC Off Until Valid Lead Condition is Detected
	  • Lead-On Detect Current: 0.7µA (typ)
	
	(MAX30003 Datasheet)

Claim 8	Accused Instrumentalities
	• Built-In Heart Rate Detection with Interrupt Feature Eliminates the Need to Run HR Algorithm on the µController • Robust R-R Detection in High Motion Environment at Extremely Low Power • Configurable Interrupts Allows the µC Wake-Up Only on Every Heart Beat Reducing the Overall System Power • High Accuracy Allows for More Physiological Data Extractions • 32-Word FIFO Allows You to Wake Up µController Every 256ms with Full ECG Acquisition • High-Speed SPI Interface • Shutdown Current of 0.5µA (typ) (MAX30003 Datasheet) **R-to-R Detection** The MAX30003 contains built-in hardware to detect R-R intervals using an adaptation of the Pan-Tompkins QRS detection algorithm[1]. The timing resolution of the R-R interval is approximately 8ms and depends on the setting of FMSTR [1:0] in CNFG_GEN (0x10) register. See Table 22 for the timing resolution of each setting. (MAX30003 Datasheet)

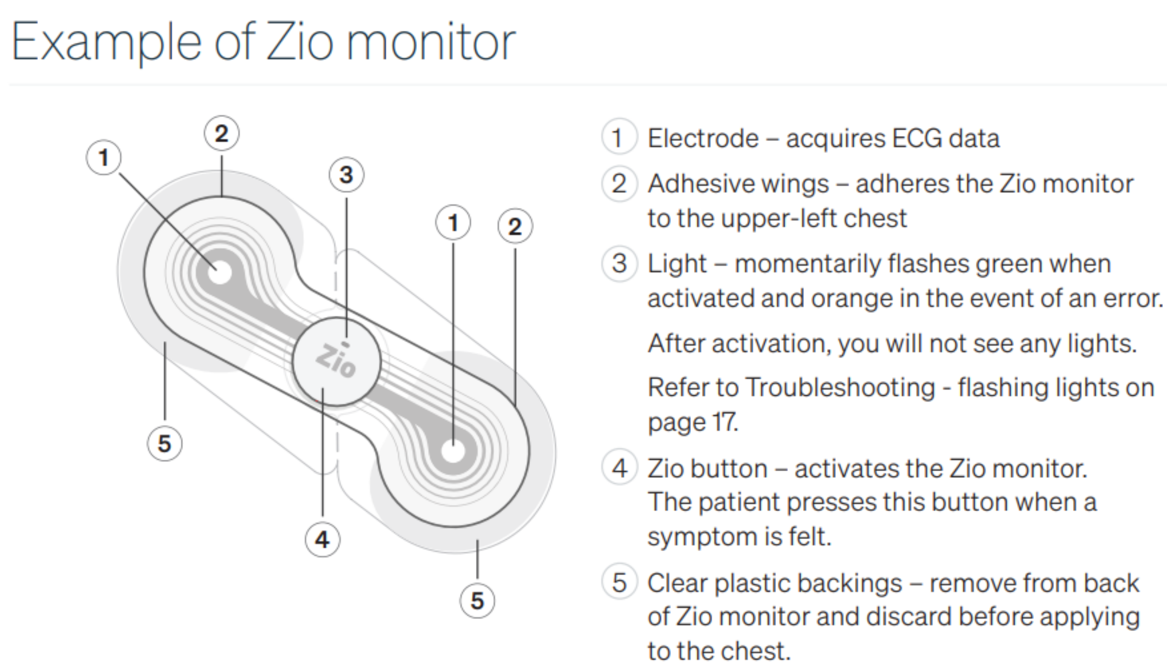
Claim 8	**Accused Instrumentalities**
	 (Zio Monitor Teardown)

Claim 8	Accused Instrumentalities
	ANALOG DEVICES Click here to ask an associate for production status of specific part numbers. MAX32665/MAX32666 Low-Power Arm Cortex-M4 with FPU-Based Microcontroller with Bluetooth 5 for Wearables **General Description** DARWIN is a new breed of low-power microcontrollers built to thrive in the rapidly evolving Internet of Things (IoT). They are smart, with the biggest memories in their class and a massively scalable memory architecture. They run forever, thanks to wearable-grade power technology. They are durable enough to withstand the most advanced cyberattacks. DARWIN microcontrollers are designed to run any application imaginable—in places where you would not dream of sending other microcontrollers. Generation UB microcontrollers are designed to handle the increasingly complex applications demanded by today's advanced battery-powered devices and wirelessly connected devices, while providing robust hardware security and Bluetooth® 5 Low Energy (Bluetooth LE) radio connectivity. The MAX32665/MAX32666 UB class microcontrollers are advanced systems-on-chips featuring an Arm® Cortex®-M4 with FPU CPU for efficient computation of complex functions and algorithms with integrated power management. It also includes the newest generation Bluetooth 5 LE radio with support for long range (4x) and high throughput (2Mbps) and ADI's best-in-class hardware security suite trust protection unit (TPU). The devices offer large on-board memory with 1MB flash and 560KB SRAM. Split flash banks of 512KB each support seamless over-the-air upgrades, adding an additional degree of reliability. Memory scalability of data (SRAM) and code (Flash) space is supported by two SPI execute-in-place (SPIX) interfaces. (MAX32666 Datasheet)

Claim 8	Accused Instrumentalities

	Multiple high-speed interfaces are supported including HS-USB, secure digital interface (SD, SDIO, MMC, SD-HC, and microSD™), SPI, UART, and I^2C serial interfaces, and an audio subsystem supporting PDM, PCM, I^2S, and TDM interfaces. An 8-input, 10-bit ADC is available to monitor analog inputs from external sensors and meters. The devices are available in 109-bump WLP (0.35mm pitch) and 121-bump CTBGA (0.65mm pitch).
	
	Applications
	• Connected Home
	• Industrial Sensors
	• Payment/Fitness/Medical Wearables
	• Telemedicine
	• Gaming Devices
	• Hearables
	
	(MAX32666 Datasheet)
	
	Benefits and Features
	• High-Efficiency Microcontroller and Audio DSP for Wearable and Hearable Devices
	  • Arm Cortex-M4 with FPU Up to 96MHz
	  • Optional Second Arm Cortex-M4 with FPU Optimized for Data Processing
	  • Low-Power, 7.3728MHz System Clock Option
	  • 1MB Flash, Organized into Dual Banks 2 x 512KB
	  • 560KB SRAM; 3 x 16KB Cache
	• Bluetooth 5 Low Energy Radio
	  • 1Mbps and 2Mbps Data Throughput
	  • Long Range (125kbps and 500kbps)
	  • Advertising Extension
	  • Rx Sensitivity: -95dbm; Tx Power Up to +4.5dbm
	  • On-Chip Matching with Single-Ended Antenna Port
	
	(MAX32666 Datasheet)

Claim 8	Accused Instrumentalities
	MAX32665/MAX32666 The MAX32665/MAX32666 are Arm Cortex-M4 with FPU-based microcontrollers with 1MB flash and 560KB SRAM. They are ideal for wearable medical fitness applications. A second Arm Cortex-M4 with FPU supporting ROM and cache supports extended data processing capabilities such as audio processing for wireless Bluetooth applications. The architecture includes a Bluetooth 5 Low Energy radio. The devices feature five powerful and flexible power modes. The flash memory is split into two banks of 512KB to provide flexibility when programming over the air. A built-in single inductor multiple output (SIMO) switch mode power supply allows the device to be optionally self-powered by a primary lithium cell. Dedicated hardware runs the Bluetooth 5 Low Energy stack freeing the CPUs for data processing tasks. Built-in dynamic clock gating and firmware-controlled power gating allow the user to optimize power for the specific application. Multiple SPI, UART, and I^2C serial interfaces, 1-Wire Master, and USB 2.0 High-Speed Device interface allow interconnection to a wide variety of external sensors. An audio subsystem supports PDM, PCM, I^2S, and TDM. An 8-input, 10-bit ADC is available to monitor analog input from external sensors and meters. The MAX32666 incorporates a trust protection unit (TPU) with encryption and advanced security features. These features include a modular arithmetic accelerator (MAA) for fast ECDSA, a hardware AES engine, a hardware TRNG entropy generator, a SHA-2 accelerator, and a secure bootloader. All devices are available in a 109-bump WLP with 0.35mm pitch and a 121-bump CTBGA with 0.65mm pitch packages. (MAX32666 Datasheet) **Arm Cortex-M4 with FPU Processor** The Arm Cortex-M4 with FPU processors CPU0 and CPU1 are ideal for the emerging category of wearable medical and wellness applications. The architecture combines high-efficiency signal processing functionality with low power, low cost, and ease of use. The Arm Cortex-M4 with FPU DSP supports single instruction multiple data (SIMD) path DSP extensions, providing: • Four parallel 8-bit add/sub • Floating point single precision • Two parallel 16-bit add/sub • Two parallel MACs • 32- or 64-bit accumulate • Signed, unsigned, data with or without saturation (MAX32666 Datasheet)

Claim 8	**Accused Instrumentalities**
8[t] wherein the processor is electrically coupled to the first electrocardiographic electrode, the second electrocardiographic electrode, and the battery,	***The Accused Instrumentalities include a processor wherein the processor is electrically coupled to the first electrocardiographic electrode, the second electrocardiographic electrode, and the battery.*** The Zio Monitor satisfies 8[t] because the Zio Monitor includes a processor that is electrically coupled to the electrodes and the battery.  (https://go.irhythmtech.com/hubfs/LB10117.01%20-%20ZIO%20MONITOR%20INSTRUCTIONS%20FOR%20USE%2c%20PRINTED%20(2).pdf)

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Claim 8	Accused Instrumentalities
	Day: From a technical viewpoint what we did was really to leverage a lot of advances not just in microprocessor efficiency, which is certainly part of it in terms of miniaturization as well as energy efficiency, but also we really challenged ourselves to figure out how to effectively fit in the smallest possible form factor, which for us was motivated a lot by the size of our battery, which is just a standard, easily available, and fortunately easily recyclable coin cell battery. We challenged ourselves to figure out how to miniaturize the device down to the level of one of those coin cells instead of the two that the Zio XT device uses. And that became feasible by the advances in microelectronic microprocessor efficiency and size as well through its miniaturization. But it also required a lot of really complicated dynamics from an electrical engineering perspective to figure out how to get all the components of a wearable medical device and a biosensor onto that small form factor. So, miniaturization was focused on very clever ways of handling some of the larger components, which for example involved moving some of the big resistors that are required on the device to the more flexible part of the patch instead of on the actual printed circuit board in the housing. And this is a patented feature that we've already received a patent on it and we're pursuing more around it, but it was the idea that these three big resistors are not too big in terms of the homage that they have but also in terms of the size that they are. So, if you put them on the circuit board, they are these pretty big components, so we realized pretty early on that we couldn't really do that and still fit the design constraints. So, we innovated a different way, which was to integrate it into the ECG tracings themselves. (https://www.mddionline.com/cardiovascular/behind-the-design-how-irhythm-built-its-new-zio-monitor)

Claim 8	Accused Instrumentalities
	The Zio Monitor, our newest model, is 72% smaller and 62% lighter relative to the previous generation. The Zio Monitor uses 1 coin-cell battery, as compared to the 2 used in Zio XT. This is the second-most environmentally impactful component of our devices (after the circuit board). While we recycle these batteries, this is still a meaningful reduction in impact. (https://go.irhythmtech.com/hubfs/LB10117.01%20-%20ZIO%20MONITOR%20INSTRUCTIONS%20FOR%20USE%2c%20PRINTED%20(2).pdf) **ZIO MONITOR SYSTEM** The Zio Monitor System is the next generation of the Zio XT System, and is a prescription-only, remote ECG monitoring system that consists of the Zio Monitor patch that records the electric signal from the heart continuously for up to 14 days and the ZEUS System, which supports the capture and analysis of ECG data recorded by the Zio Monitor patch at the end of the wear period, including specific arrhythmia events detected by the ZEUS algorithm. (https://go.irhythmtech.com/hubfs/LB10117.01%20-%20ZIO%20MONITOR%20INSTRUCTIONS%20FOR%20USE%2c%20PRINTED%20(2).pdf)

Claim 8	**Accused Instrumentalities**
	 (Zio Monitor Teardown)  (Zio Monitor Teardown)

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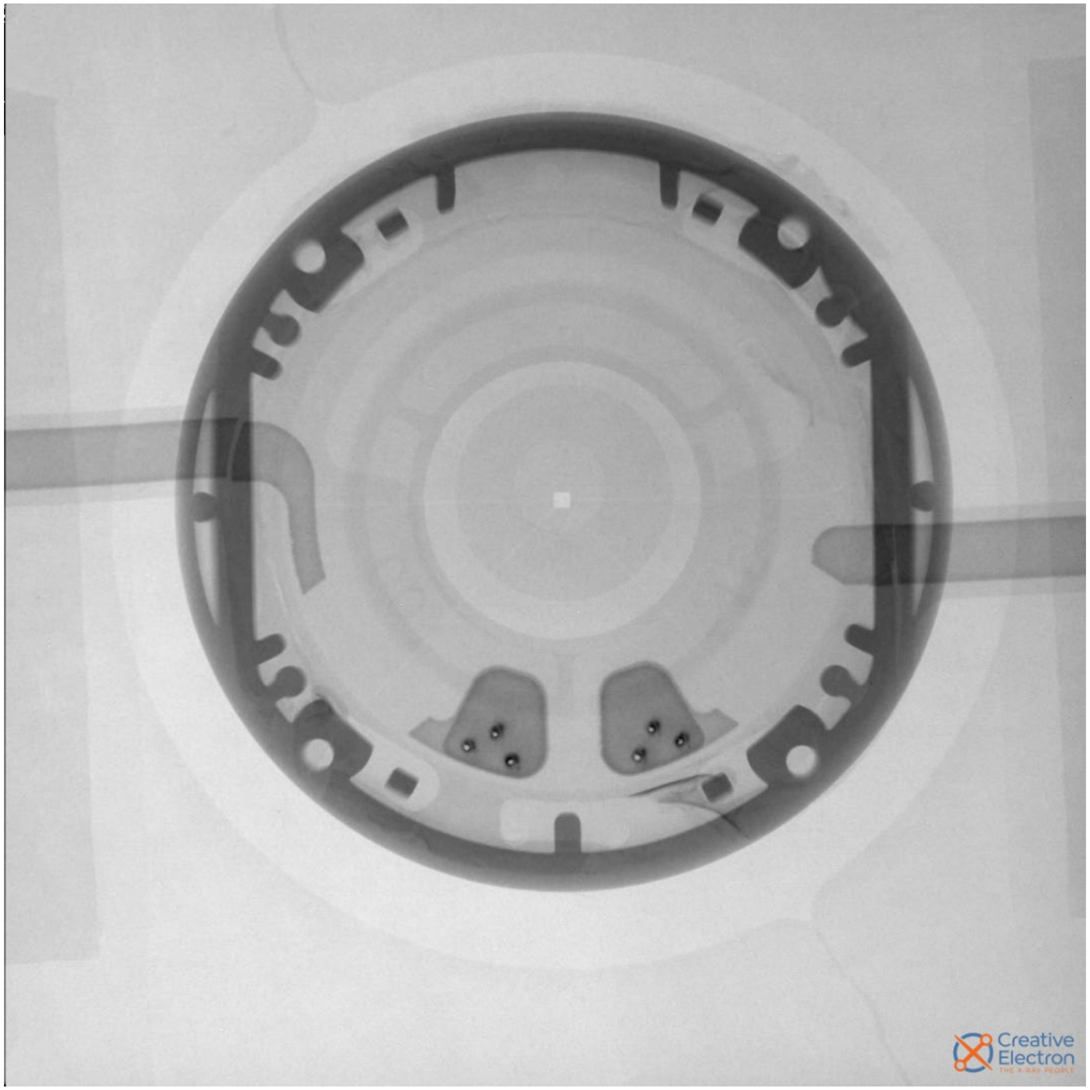
Claim 8	**Accused Instrumentalities**
	 (Zio Monitor Teardown)

Claim 8	Accused Instrumentalities
	 (Zio Monitor Teardown)

Claim 8	Accused Instrumentalities
	 (Zio Monitor Teardown)  (Zio Monitor Teardown)

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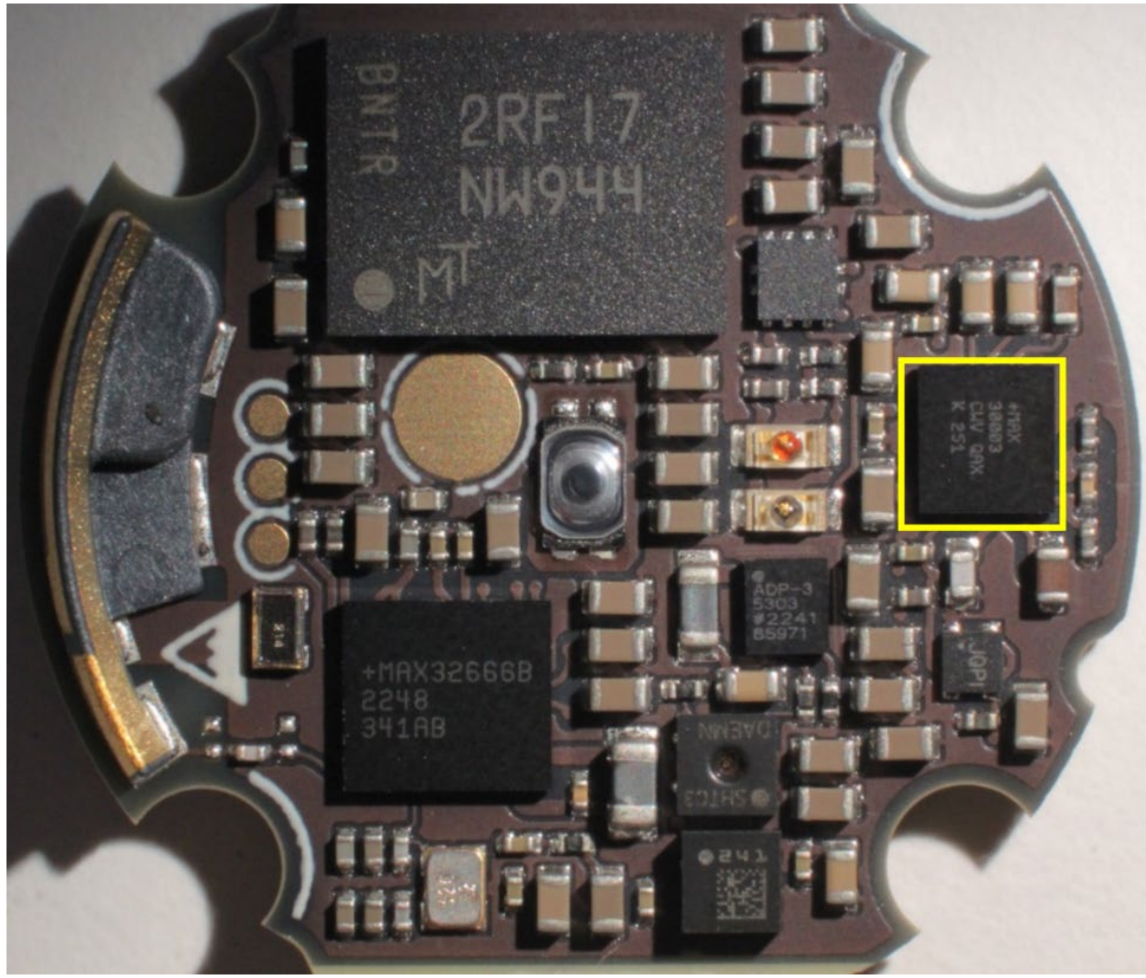
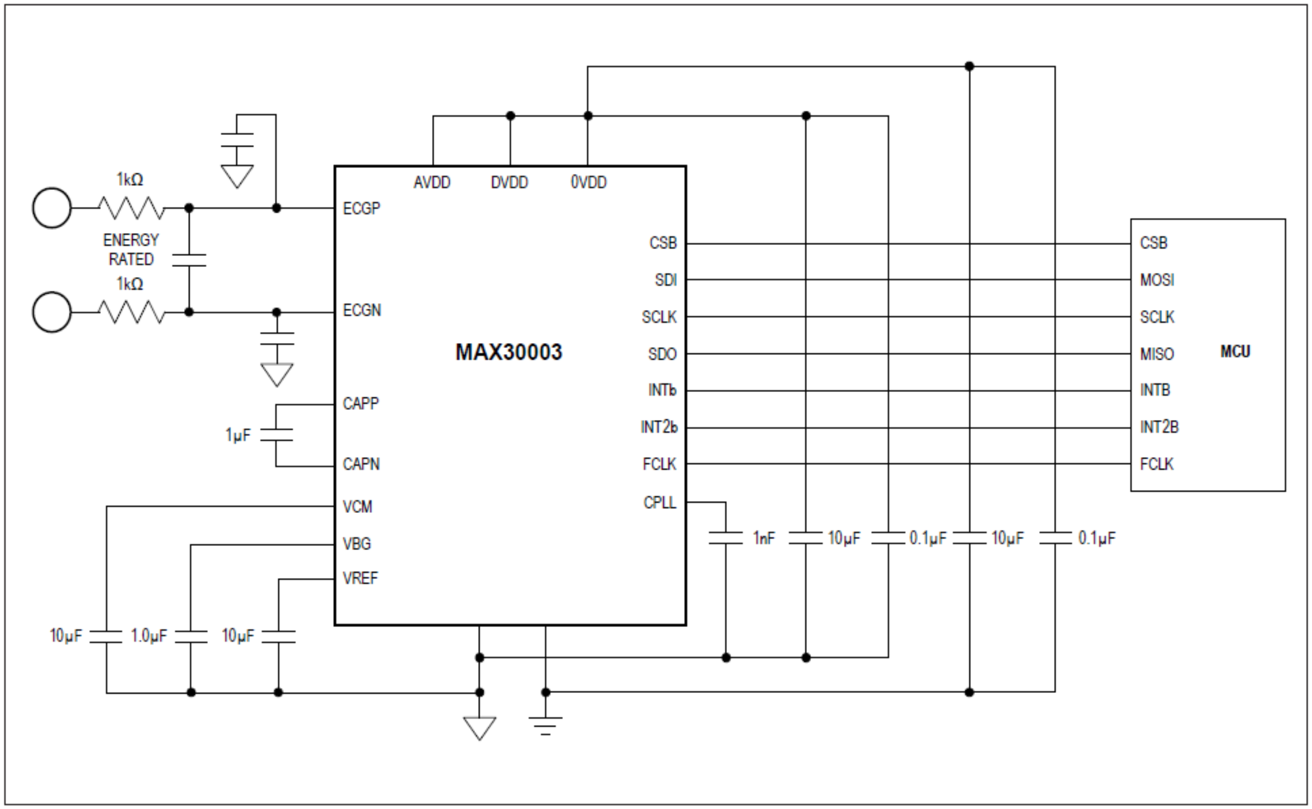
Claim 8	Accused Instrumentalities
	 (Zio Monitor Teardown)

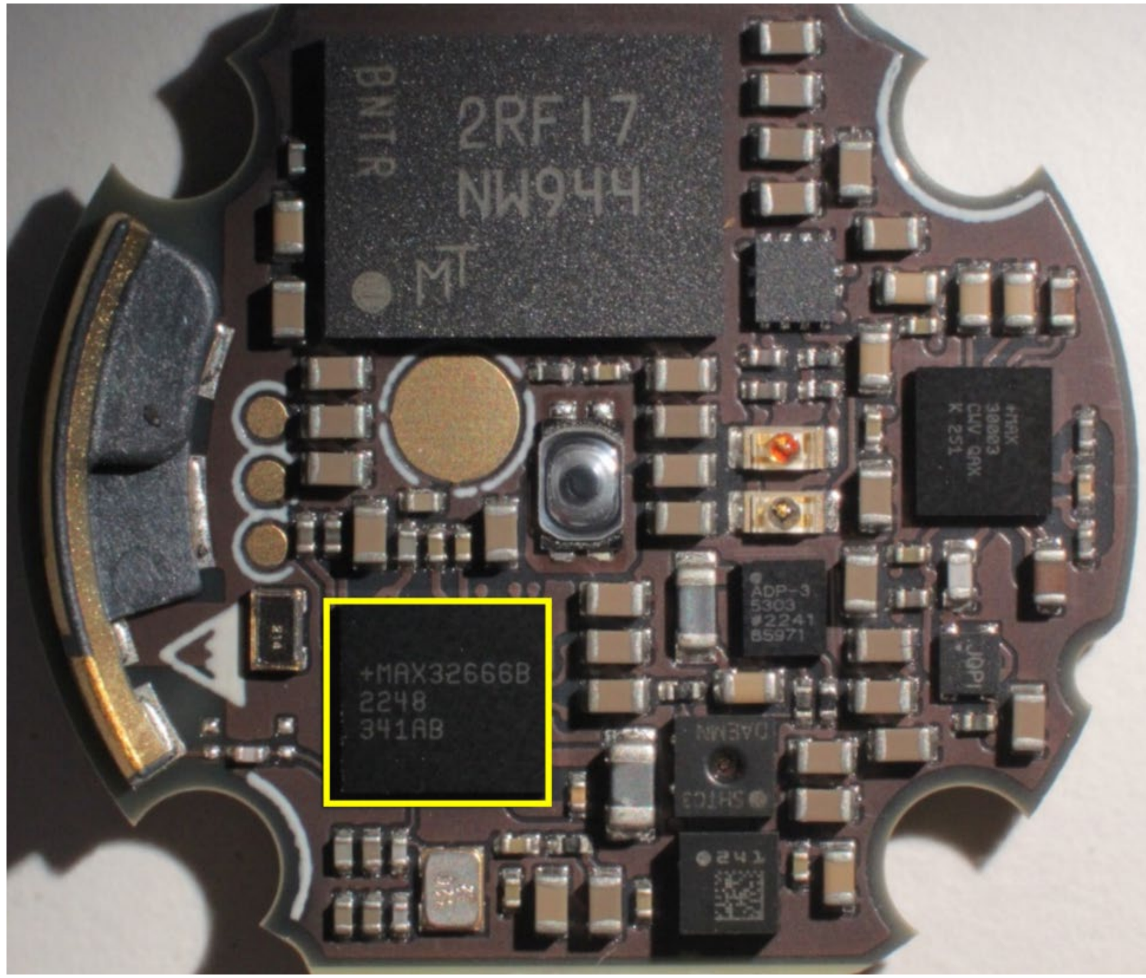
Claim 8	Accused Instrumentalities
	 (MAX30003 Datasheet)

Claim 8	**Accused Instrumentalities**
	ANALOG DEVICES Evaluation Kit Available · Design Resources · Tools and Models · Support *Click here to ask an associate for production status of specific part numbers.* **Ultra-Low Power, Single-Channel Integrated Biopotential (ECG, R-to-R Detection) AFE** **MAX30003** **General Description** The MAX30003 is a complete, biopotential, analog front-end solution for wearable applications. It offers high performance for clinical and fitness applications, with ultra-low power for long battery life. The MAX30003 is a single biopotential channel providing ECG waveforms and heart rate detection. The biopotential channel has ESD protection, EMI filtering, internal lead biasing, DC leads-off detection, ultra-low power leads-on detection during standby mode, and extensive calibration voltages for built-in self-test. Soft power-up sequencing ensures no large transients are injected into the electrodes. The biopotential channel also has high input impedance, low noise, high CMRR, programmable gain, various low-pass and high-pass filter options, and a high resolution analog-to-digital converter. The biopotential channel is DC coupled, can handle large electrode voltage offsets, and has a fast recovery mode to quickly recover from overdrive conditions, such as defibrillation and electrosurgery. The MAX30003 is available in a 28-pin TQFN and 30-bump wafer-level package (WLP), operating over the 0°C to +70°C commercial temperature range. (MAX30003 Datasheet)

Claim 8	**Accused Instrumentalities**

	Benefits and Features
	• Clinical-Grade ECG AFE with High-Resolution Data Converter
	  • 15.5 Bits Effective Resolution with 5µV_{P-P} Noise
	• Better Dry Starts Due to Much Improved Real World CMRR and High Input Impedance
	  • Fully Differential Input Structure with CMRR > 100dB
	• Offers Better Common-Mode to Differential Mode Conversion Due to High Input Impedance
	  • High Input Impedance > 500MΩ for Extremely Low Common-to-Differential Mode Conversion
	• Minimum Signal Attenuation at the Input During Dry Start Due to High Electrode Impedance
	• High DC Offset Range of ±650mV (1.8V, typ) Allows to Be Used with Wide Variety of Electrodes
	• High AC Dynamic Range of 65mV_{P-P} Will Help the AFE Not Saturate in the Presence of Motion/Direct Electrode Hits
	• Longer Battery Life Compared to Competing Solutions
	  • 85µW at 1.1V Supply Voltage
	• Leads-On Interrupt Feature Allows to Keep µC in Deep Sleep Mode with RTC Off Until Valid Lead Condition is Detected
	  • Lead-On Detect Current: 0.7µA (typ)
	
	(MAX30003 Datasheet)

Claim 8	Accused Instrumentalities
	• Built-In Heart Rate Detection with Interrupt Feature Eliminates the Need to Run HR Algorithm on the µController • Robust R-R Detection in High Motion Environment at Extremely Low Power • Configurable Interrupts Allows the µC Wake-Up Only on Every Heart Beat Reducing the Overall System Power • High Accuracy Allows for More Physiological Data Extractions • 32-Word FIFO Allows You to Wake Up µController Every 256ms with Full ECG Acquisition • High-Speed SPI Interface • Shutdown Current of 0.5µA (typ) (MAX30003 Datasheet) **R-to-R Detection** The MAX30003 contains built-in hardware to detect R-R intervals using an adaptation of the Pan-Tompkins QRS detection algorithm[1]. The timing resolution of the R-R interval is approximately 8ms and depends on the setting of FMSTR [1:0] in CNFG_GEN (0x10) register. See Table 22 for the timing resolution of each setting. (MAX30003 Datasheet)

Claim 8	**Accused Instrumentalities**
	 (Zio Monitor Teardown)

<table>
<tr><th><u>Claim 8</u></th><th><u>Accused Instrumentalities</u></th></tr>
<tr><td></td><td>
ANALOG DEVICES
Click here to ask an associate for production status of specific part numbers.
MAX32665/MAX32666 Low-Power Arm Cortex-M4 with FPU-Based Microcontroller with Bluetooth 5 for Wearables

General Description
DARWIN is a new breed of low-power microcontrollers built to thrive in the rapidly evolving Internet of Things (IoT). They are smart, with the biggest memories in their class and a massively scalable memory architecture. They run forever, thanks to wearable-grade power technology. They are durable enough to withstand the most advanced cyberattacks. DARWIN microcontrollers are designed to run any application imaginable—in places where you would not dream of sending other microcontrollers.

Generation UB microcontrollers are designed to handle the increasingly complex applications demanded by today's advanced battery-powered devices and wirelessly connected devices, while providing robust hardware security and Bluetooth® 5 Low Energy (Bluetooth LE) radio connectivity.

The MAX32665/MAX32666 UB class microcontrollers are advanced systems-on-chips featuring an Arm® Cortex®-M4 with FPU CPU for efficient computation of complex functions and algorithms with integrated power management. It also includes the newest generation Bluetooth 5 LE radio with support for long range (4x) and high throughput (2Mbps) and ADI's best-in-class hardware security suite trust protection unit (TPU). The devices offer large on-board memory with 1MB flash and 560KB SRAM. Split flash banks of 512KB each support seamless over-the-air upgrades, adding an additional degree of reliability. Memory scalability of data (SRAM) and code (Flash) space is supported by two SPI execute-in-place (SPIX) interfaces.

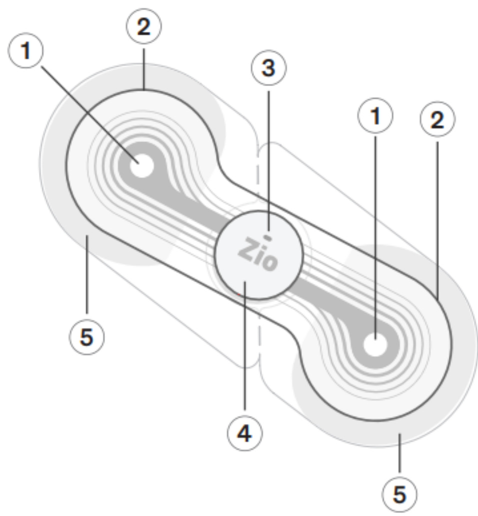
(MAX32666 Datasheet)
</td></tr>
</table>

Claim 8	Accused Instrumentalities

	Multiple high-speed interfaces are supported including HS-USB, secure digital interface (SD, SDIO, MMC, SD-HC, and microSD™), SPI, UART, and I²C serial interfaces, and an audio subsystem supporting PDM, PCM, I²S, and TDM interfaces. An 8-input, 10-bit ADC is available to monitor analog inputs from external sensors and meters. The devices are available in 109-bump WLP (0.35mm pitch) and 121-bump CTBGA (0.65mm pitch).
	
	Applications
	• Connected Home
	• Industrial Sensors
	• Payment/Fitness/Medical Wearables
	• Telemedicine
	• Gaming Devices
	• Hearables
	
	(MAX32666 Datasheet)
	
	Benefits and Features
	• High-Efficiency Microcontroller and Audio DSP for Wearable and Hearable Devices
	  • Arm Cortex-M4 with FPU Up to 96MHz
	  • Optional Second Arm Cortex-M4 with FPU Optimized for Data Processing
	  • Low-Power, 7.3728MHz System Clock Option
	  • 1MB Flash, Organized into Dual Banks 2 x 512KB
	  • 560KB SRAM; 3 x 16KB Cache
	• Bluetooth 5 Low Energy Radio
	  • 1Mbps and 2Mbps Data Throughput
	  • Long Range (125kbps and 500kbps)
	  • Advertising Extension
	  • Rx Sensitivity: -95dbm; Tx Power Up to +4.5dbm
	  • On-Chip Matching with Single-Ended Antenna Port
	
	(MAX32666 Datasheet)

Claim 8	Accused Instrumentalities
	MAX32665/MAX32666 The MAX32665/MAX32666 are Arm Cortex-M4 with FPU-based microcontrollers with 1MB flash and 560KB SRAM. They are ideal for wearable medical fitness applications. A second Arm Cortex-M4 with FPU supporting ROM and cache supports extended data processing capabilities such as audio processing for wireless Bluetooth applications. The architecture includes a Bluetooth 5 Low Energy radio. The devices feature five powerful and flexible power modes. The flash memory is split into two banks of 512KB to provide flexibility when programming over the air. A built-in single inductor multiple output (SIMO) switch mode power supply allows the device to be optionally self-powered by a primary lithium cell. Dedicated hardware runs the Bluetooth 5 Low Energy stack freeing the CPUs for data processing tasks. Built-in dynamic clock gating and firmware-controlled power gating allow the user to optimize power for the specific application. Multiple SPI, UART, and I^2C serial interfaces, 1-Wire Master, and USB 2.0 High-Speed Device interface allow interconnection to a wide variety of external sensors. An audio subsystem supports PDM, PCM, I^2S, and TDM. An 8-input, 10-bit ADC is available to monitor analog input from external sensors and meters. The MAX32666 incorporates a trust protection unit (TPU) with encryption and advanced security features. These features include a modular arithmetic accelerator (MAA) for fast ECDSA, a hardware AES engine, a hardware TRNG entropy generator, a SHA-2 accelerator, and a secure bootloader. All devices are available in a 109-bump WLP with 0.35mm pitch and a 121-bump CTBGA with 0.65mm pitch packages. (MAX32666 Datasheet) **Arm Cortex-M4 with FPU Processor** The Arm Cortex-M4 with FPU processors CPU0 and CPU1 are ideal for the emerging category of wearable medical and wellness applications. The architecture combines high-efficiency signal processing functionality with low power, low cost, and ease of use. The Arm Cortex-M4 with FPU DSP supports single instruction multiple data (SIMD) path DSP extensions, providing: • Four parallel 8-bit add/sub • Floating point single precision • Two parallel 16-bit add/sub • Two parallel MACs • 32- or 64-bit accumulate • Signed, unsigned, data with or without saturation (MAX32666 Datasheet)

Claim 8	Accused Instrumentalities
8[u] wherein the processor is configured to process the electrocardiographic signals sensed via the first electrocardiographic electrode and the second electrocardiographic electrode.	***The Accused Instrumentalities include a processor wherein the processor is configured to process the electrocardiographic signals sensed via the first electrocardiographic electrode and the second electrocardiographic electrode.*** The Zio Monitor satisfies 8[u] because the Zio Monitor's processor processes electrocardiographic signals sensed by its electrocardiographic electrodes. **Product Description** The Zio® ECG Monitoring System is an ambulatory Electrocardiogram (ECG) monitoring system. The Zio ECG Monitoring System consists of two components: (1) Zio monitor (2) proprietary algorithm software. The Zio monitor is a single-use ECG monitor that provides a continuous, single-channel recording for up to 14 days. The Zio monitor records ECG data without patient interaction, with the goal of improving patient compliance via simplicity of operation. Patients have the option of pressing a convenient button and filling out a log to document symptomatic events, which will support symptom-rhythm correlation in the diagnostic report. After conclusion of the wear period (up to 14 days), the patient removes the Zio monitor and returns it by mail to iRhythm for processing. After receipt, the data is analyzed by iRhythm's proprietary algorithm before a Certified Cardiographic Technician (CCT) reviews the results and generates a report of the key findings. (https://go.irhythmtech.com/hubfs/LB10117.01%20-%20ZIO%20MONITOR%20INSTRUCTIONS%20FOR%20USE%2c%20PRINTED%20(2).pdf)

Claim 8	**Accused Instrumentalities**
	Example of Zio monitor  1 Electrode – acquires ECG data 2 Adhesive wings – adheres the Zio monitor to the upper-left chest 3 Light – momentarily flashes green when activated and orange in the event of an error. After activation, you will not see any lights. Refer to Troubleshooting - flashing lights on page 17. 4 Zio button – activates the Zio monitor. The patient presses this button when a symptom is felt. 5 Clear plastic backings – remove from back of Zio monitor and discard before applying to the chest. https://go.irhythmtech.com/hubfs/LB10117.01%20-%20ZIO%20MONITOR%20INSTRUCTIONS%20FOR%20USE%2c%20PRINTED%20(2).pdf

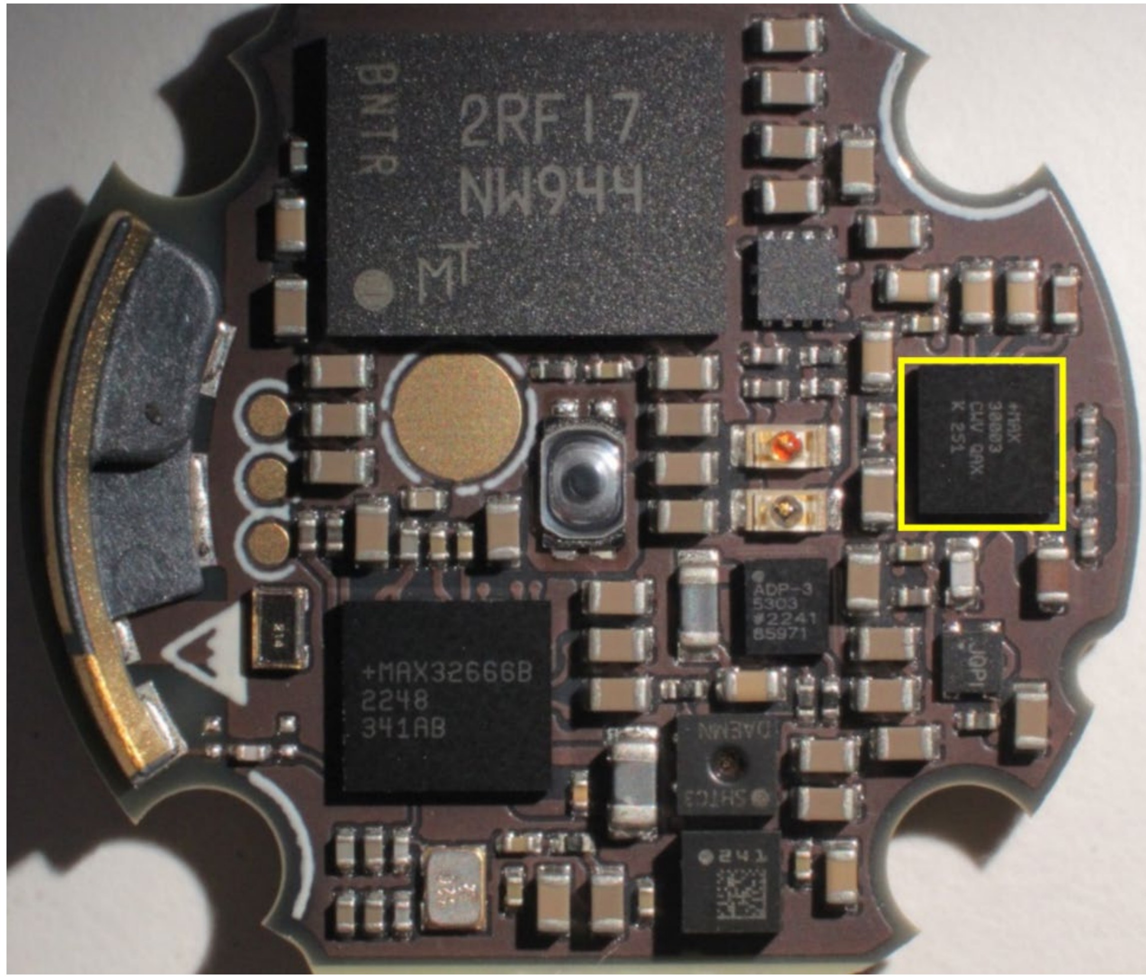
321819903.2

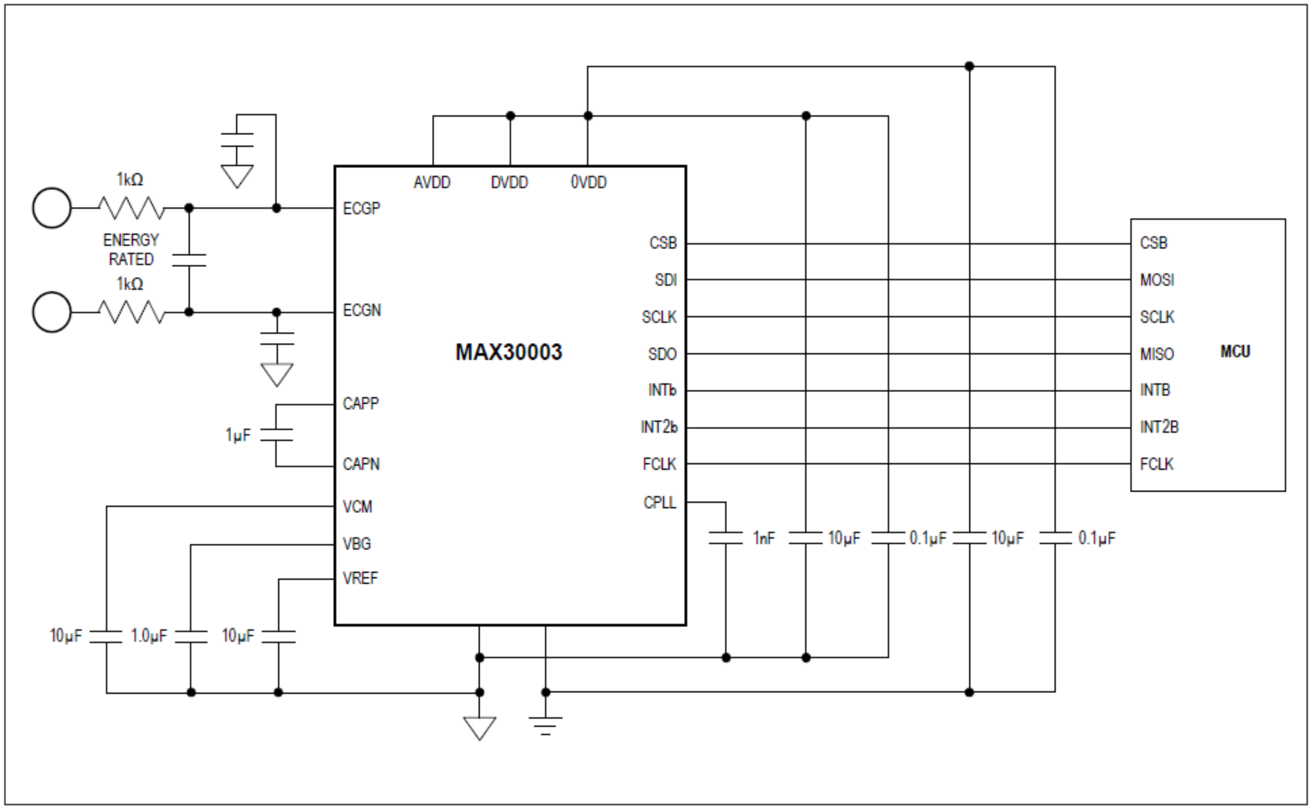
Claim 8	Accused Instrumentalities
	ZIO MONITOR SYSTEM The Zio Monitor System is the next generation of the Zio XT System, and is a prescription-only, remote ECG monitoring system that consists of the Zio Monitor patch that records the electric signal from the heart continuously for up to 14 days and the ZEUS System, which supports the capture and analysis of ECG data recorded by the Zio Monitor patch at the end of the wear period, including specific arrhythmia events detected by the ZEUS algorithm. (https://go.irhythmtech.com/hubfs/LB10117.01%20-%20ZIO%20MONITOR%20INSTRUCTIONS%20FOR%20USE%2c%20PRINTED%20(2).pdf) Zio Monitor Zio XT Zio AT Long-term continuous monitoring service The new Zio monitor is designed with patients in mind by providing a more breathable, inconspicuous, and comfortable wear experience so patients can go about their daily activities.[5,15,16] (https://www.irhythmtech.com/providers/zio-service/zio-monitors)

Claim 8	Accused Instrumentalities
	 (Zio Monitor Teardown)  (Zio Monitor Teardown)

321819903.2

Claim 8	**Accused Instrumentalities**
	 (Zio Monitor Teardown)  (Zio Monitor Teardown)

Claim 8	Accused Instrumentalities
	 (Zio Monitor Teardown)

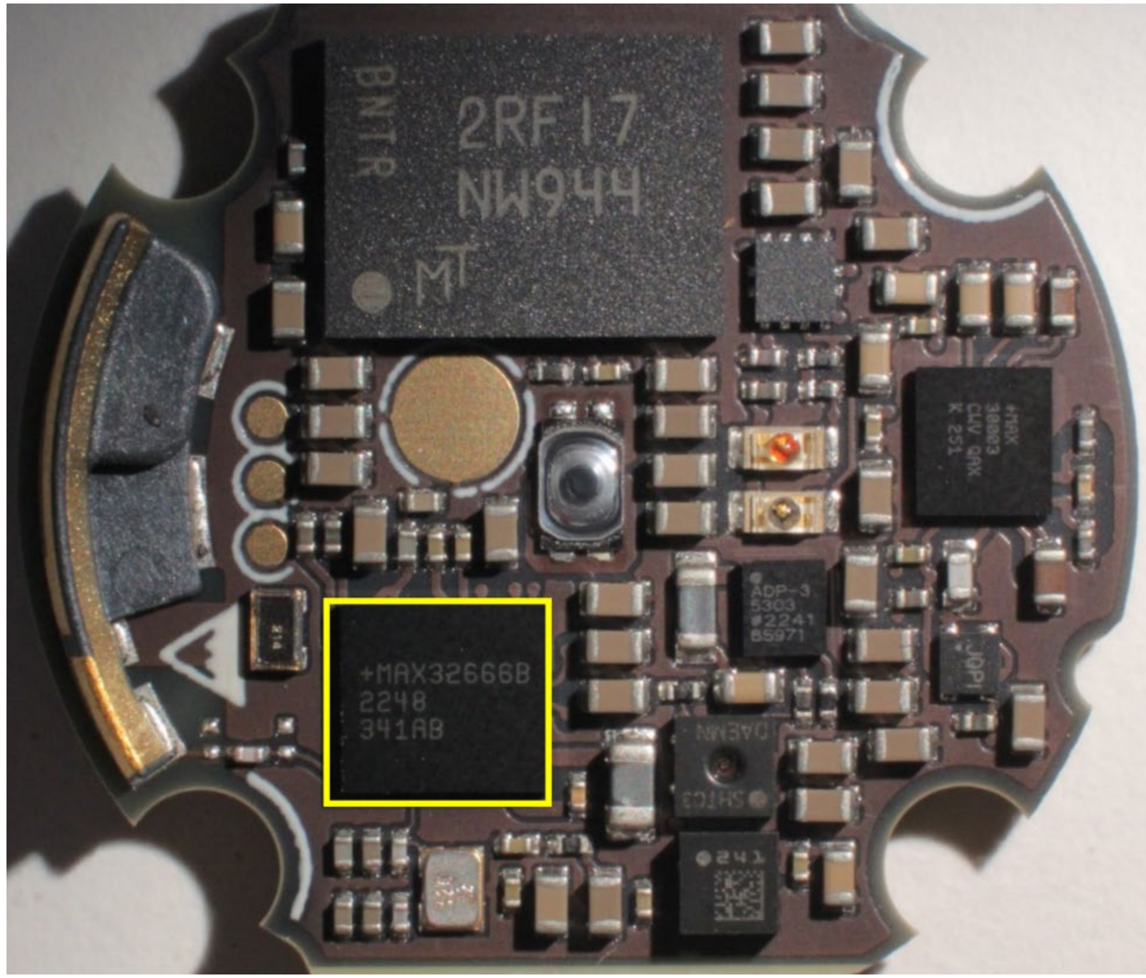
Claim 8	Accused Instrumentalities
	 (MAX30003 Datasheet)

Claim 8	Accused Instrumentalities
	ANALOG DEVICES Evaluation Kit Available · Design Resources · Tools and Models · Support *Click here to ask an associate for production status of specific part numbers.* **Ultra-Low Power, Single-Channel Integrated Biopotential (ECG, R-to-R Detection) AFE** **MAX30003** **General Description** The MAX30003 is a complete, biopotential, analog front-end solution for wearable applications. It offers high performance for clinical and fitness applications, with ultra-low power for long battery life. The MAX30003 is a single biopotential channel providing ECG waveforms and heart rate detection. The biopotential channel has ESD protection, EMI filtering, internal lead biasing, DC leads-off detection, ultra-low power leads-on detection during standby mode, and extensive calibration voltages for built-in self-test. Soft power-up sequencing ensures no large transients are injected into the electrodes. The biopotential channel also has high input impedance, low noise, high CMRR, programmable gain, various low-pass and high-pass filter options, and a high resolution analog-to-digital converter. The biopotential channel is DC coupled, can handle large electrode voltage offsets, and has a fast recovery mode to quickly recover from overdrive conditions, such as defibrillation and electrosurgery. The MAX30003 is available in a 28-pin TQFN and 30-bump wafer-level package (WLP), operating over the 0°C to +70°C commercial temperature range. (MAX30003 Datasheet)

Claim 8	Accused Instrumentalities

	Benefits and Features
	• Clinical-Grade ECG AFE with High-Resolution Data Converter
	  • 15.5 Bits Effective Resolution with 5μV_{P-P} Noise
	• Better Dry Starts Due to Much Improved Real World CMRR and High Input Impedance
	  • Fully Differential Input Structure with CMRR > 100dB
	• Offers Better Common-Mode to Differential Mode Conversion Due to High Input Impedance
	  • High Input Impedance > 500MΩ for Extremely Low Common-to-Differential Mode Conversion
	• Minimum Signal Attenuation at the Input During Dry Start Due to High Electrode Impedance
	• High DC Offset Range of ±650mV (1.8V, typ) Allows to Be Used with Wide Variety of Electrodes
	• High AC Dynamic Range of 65mV_{P-P} Will Help the AFE Not Saturate in the Presence of Motion/Direct Electrode Hits
	• Longer Battery Life Compared to Competing Solutions
	  • 85μW at 1.1V Supply Voltage
	• Leads-On Interrupt Feature Allows to Keep μC in Deep Sleep Mode with RTC Off Until Valid Lead Condition is Detected
	  • Lead-On Detect Current: 0.7μA (typ)
	
	(MAX30003 Datasheet)

Claim 8	Accused Instrumentalities
	• Built-In Heart Rate Detection with Interrupt Feature Eliminates the Need to Run HR Algorithm on the µController • Robust R-R Detection in High Motion Environment at Extremely Low Power • Configurable Interrupts Allows the µC Wake-Up Only on Every Heart Beat Reducing the Overall System Power • High Accuracy Allows for More Physiological Data Extractions • 32-Word FIFO Allows You to Wake Up µController Every 256ms with Full ECG Acquisition • High-Speed SPI Interface • Shutdown Current of 0.5µA (typ) (MAX30003 Datasheet) **R-to-R Detection** The MAX30003 contains built-in hardware to detect R-R intervals using an adaptation of the Pan-Tompkins QRS detection algorithm[1]. The timing resolution of the R-R interval is approximately 8ms and depends on the setting of FMSTR [1:0] in CNFG_GEN (0x10) register. See Table 22 for the timing resolution of each setting. (MAX30003 Datasheet)

Claim 8	**Accused Instrumentalities**
	 (Zio Monitor Teardown)

Claim 8	Accused Instrumentalities
	ANALOG DEVICES Click here to ask an associate for production status of specific part numbers. MAX32665/MAX32666 Low-Power Arm Cortex-M4 with FPU-Based Microcontroller with Bluetooth 5 for Wearables **General Description** DARWIN is a new breed of low-power microcontrollers built to thrive in the rapidly evolving Internet of Things (IoT). They are smart, with the biggest memories in their class and a massively scalable memory architecture. They run forever, thanks to wearable-grade power technology. They are durable enough to withstand the most advanced cyberattacks. DARWIN microcontrollers are designed to run any application imaginable—in places where you would not dream of sending other microcontrollers. Generation UB microcontrollers are designed to handle the increasingly complex applications demanded by today's advanced battery-powered devices and wirelessly connected devices, while providing robust hardware security and Bluetooth® 5 Low Energy (Bluetooth LE) radio connectivity. The MAX32665/MAX32666 UB class microcontrollers are advanced systems-on-chips featuring an Arm® Cortex®-M4 with FPU CPU for efficient computation of complex functions and algorithms with integrated power management. It also includes the newest generation Bluetooth 5 LE radio with support for long range (4x) and high throughput (2Mbps) and ADI's best-in-class hardware security suite trust protection unit (TPU). The devices offer large on-board memory with 1MB flash and 560KB SRAM. Split flash banks of 512KB each support seamless over-the-air upgrades, adding an additional degree of reliability. Memory scalability of data (SRAM) and code (Flash) space is supported by two SPI execute-in-place (SPIX) interfaces. (MAX32666 Datasheet)

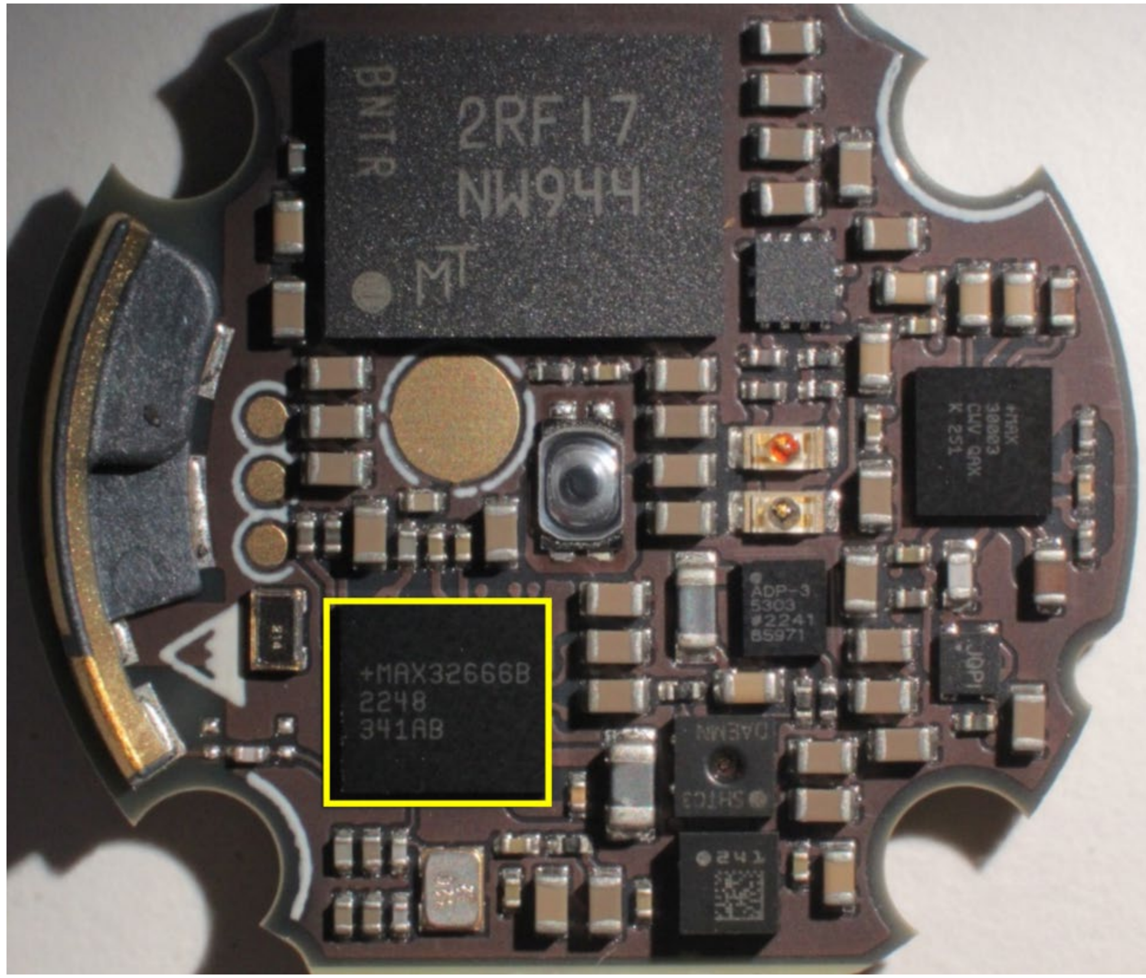
Claim 8	Accused Instrumentalities

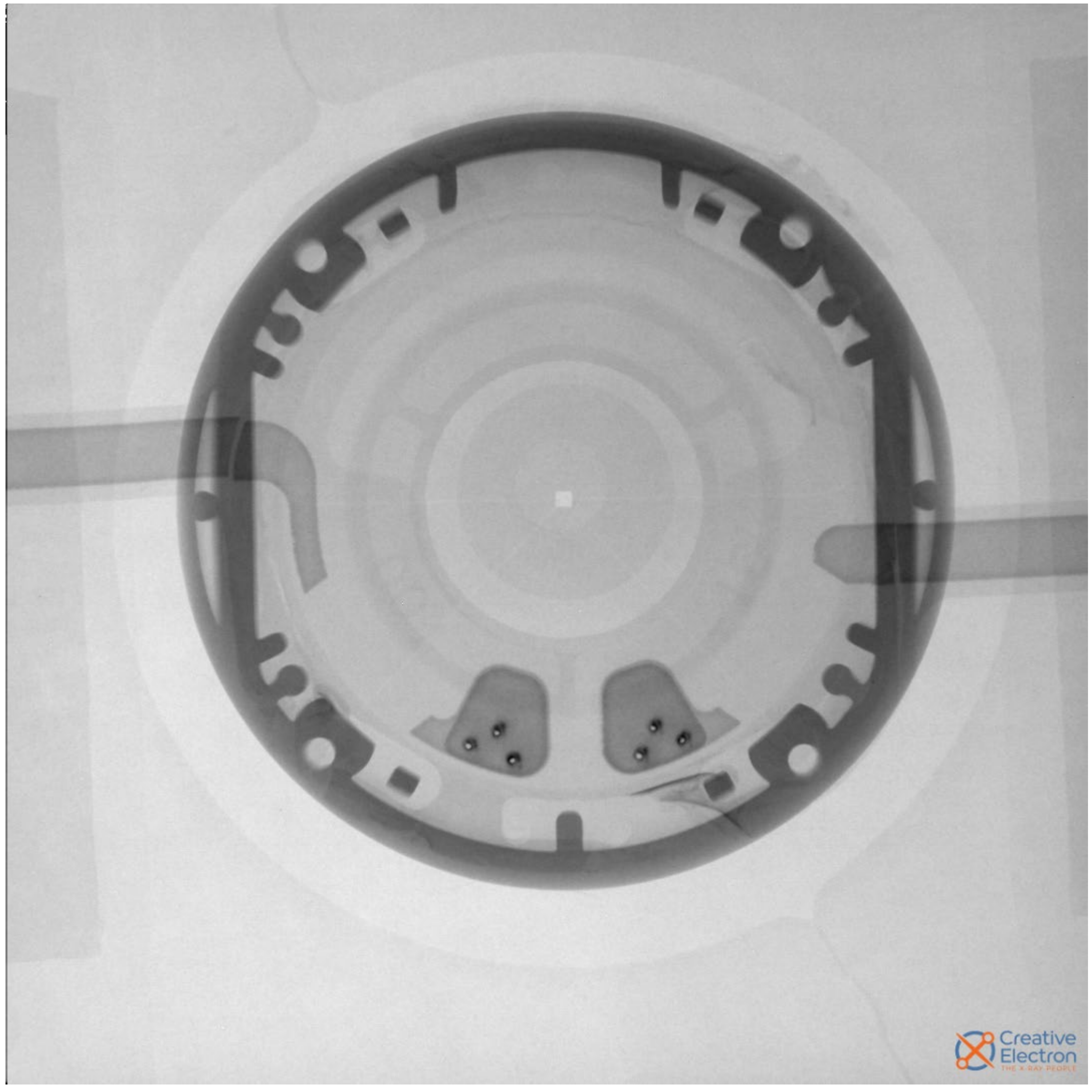
	Multiple high-speed interfaces are supported including HS-USB, secure digital interface (SD, SDIO, MMC, SD-HC, and microSD™), SPI, UART, and I^2C serial interfaces, and an audio subsystem supporting PDM, PCM, I^2S, and TDM interfaces. An 8-input, 10-bit ADC is available to monitor analog inputs from external sensors and meters. The devices are available in 109-bump WLP (0.35mm pitch) and 121-bump CTBGA (0.65mm pitch).
	
	Applications
	• Connected Home
	• Industrial Sensors
	• Payment/Fitness/Medical Wearables
	• Telemedicine
	• Gaming Devices
	• Hearables
	
	(MAX32666 Datasheet)
	
	Benefits and Features
	• High-Efficiency Microcontroller and Audio DSP for Wearable and Hearable Devices
	  • Arm Cortex-M4 with FPU Up to 96MHz
	  • Optional Second Arm Cortex-M4 with FPU Optimized for Data Processing
	  • Low-Power, 7.3728MHz System Clock Option
	  • 1MB Flash, Organized into Dual Banks 2 x 512KB
	  • 560KB SRAM; 3 x 16KB Cache
	• Bluetooth 5 Low Energy Radio
	  • 1Mbps and 2Mbps Data Throughput
	  • Long Range (125kbps and 500kbps)
	  • Advertising Extension
	  • Rx Sensitivity: -95dbm; Tx Power Up to +4.5dbm
	  • On-Chip Matching with Single-Ended Antenna Port
	
	(MAX32666 Datasheet)

Claim 8	Accused Instrumentalities
	MAX32665/MAX32666 The MAX32665/MAX32666 are Arm Cortex-M4 with FPU-based microcontrollers with 1MB flash and 560KB SRAM. They are ideal for wearable medical fitness applications. A second Arm Cortex-M4 with FPU supporting ROM and cache supports extended data processing capabilities such as audio processing for wireless Bluetooth applications. The architecture includes a Bluetooth 5 Low Energy radio. The devices feature five powerful and flexible power modes. The flash memory is split into two banks of 512KB to provide flexibility when programming over the air. A built-in single inductor multiple output (SIMO) switch mode power supply allows the device to be optionally self-powered by a primary lithium cell. Dedicated hardware runs the Bluetooth 5 Low Energy stack freeing the CPUs for data processing tasks. Built-in dynamic clock gating and firmware-controlled power gating allow the user to optimize power for the specific application. Multiple SPI, UART, and I^2C serial interfaces, 1-Wire Master, and USB 2.0 High-Speed Device interface allow interconnection to a wide variety of external sensors. An audio subsystem supports PDM, PCM, I^2S, and TDM. An 8-input, 10-bit ADC is available to monitor analog input from external sensors and meters. The MAX32666 incorporates a trust protection unit (TPU) with encryption and advanced security features. These features include a modular arithmetic accelerator (MAA) for fast ECDSA, a hardware AES engine, a hardware TRNG entropy generator, a SHA-2 accelerator, and a secure bootloader. All devices are available in a 109-bump WLP with 0.35mm pitch and a 121-bump CTBGA with 0.65mm pitch packages. (MAX32666 Datasheet) **Arm Cortex-M4 with FPU Processor** The Arm Cortex-M4 with FPU processors CPU0 and CPU1 are ideal for the emerging category of wearable medical and wellness applications. The architecture combines high-efficiency signal processing functionality with low power, low cost, and ease of use. The Arm Cortex-M4 with FPU DSP supports single instruction multiple data (SIMD) path DSP extensions, providing: • Four parallel 8-bit add/sub • Floating point single precision • Two parallel 16-bit add/sub • Two parallel MACs • 32- or 64-bit accumulate • Signed, unsigned, data with or without saturation (MAX32666 Datasheet)

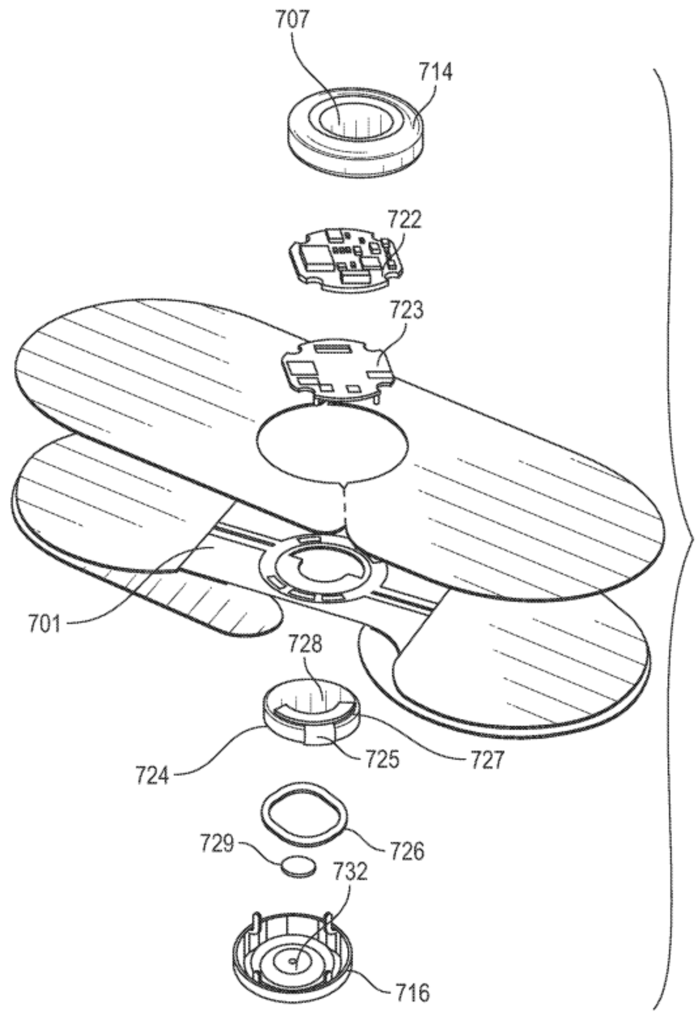
Claim 9	Accused Instrumentalities
9. The wearable electrocardiography monitoring device of Claim 8, wherein the battery is vertically aligned with the sealed housing.	***The Accused Instrumentalities include the wearable electrocardiography monitoring device of Claim 8, wherein the battery is vertically aligned with the sealed housing.*** The Zio Monitor satisfies Claim 9 because the Zio Monitor includes a battery that is located in the sealed housing, and is, therefore, vertically aligned with the sealed housing. *See* 8[n].  (Zio Monitor Teardown)

Claim 9	Accused Instrumentalities
	 (Zio Monitor Teardown)

Claim 9	**Accused Instrumentalities**
	 (Zio Monitor Teardown)

Claim 9	Accused Instrumentalities
	 (Zio Monitor Teardown)

Claim 9	**Accused Instrumentalities**
	This web page is provided to satisfy the virtual patent marking provisions of various jurisdictions including the virtual patent marking provisions of the America Invents Act and provide notice under 35 U.S.C. §287(a), that the iRhythm Technologies' Zio patch products and related services, including but not limited to the Zio patch, Zio XT, Zio AT, and Zio MCT trademarked products, are covered by or for use under one or more of the patents listed below. Zio patch products and related services are covered by or for use under one or more international patents or international patent applications. Zio patch products and related services not listed here may be protected by one or more patents in the United States and other international jurisdictions and may be covered by patents in the United States and other international jurisdictions that are not listed. iRhythm Technologies' Zio patch products and related services may be sold individually or as part of a combination product or system. US Patent Numbers*: 8,538,503; 8,560,046; 9,173,670; 9,241,649; 9,451,975; 9,597,004; 9,955,887; 10,098,559; 10,271,754; 10,299,691; D852965; D854167; 10,405,799; 10,517,500; 11,141,091; 10,555,683; 11,627,902; 11,051,738; 10,667,712; 10,813,565; 11,605,458; 11,289,197; 11,350,864; 11,350,865; 11,589,792; 11,337,632; 11,504,041; 11,246,523; 11,399,760; 11,246,524; 11,382,555; 11,083,371; 11,253,185; 11,253,186; 11,375,941 and 11,497,432. Additional patents are pending in the United States. (https://www.irhythmtech.com/content/patents-trademarks)

Claim 9	Accused Instrumentalities
	 FIG. 6H (https://patentimages.storage.googleapis.com/0f/68/ad/d5456996abdaf3/US11589792B1.pdf)

<u>**Claim 9**</u>	<u>**Accused Instrumentalities**</u>
	springs connected to the circuit board. Battery terminal **725**, may be positioned below the flexible body **701** and circuit boards **722**, thereby overlying wave spring **726**. In embodiments, the battery terminal **725** may be wrapped around and adhered to a coin cell battery **728**. The battery terminal **725** may be constructed as a flex circuit with conductive vias **727** that enables the positive underside of the coin cell battery **728** to be brought up to the negative top side of the battery, so that both the negative and positive terminals are presented on the top side of the battery to meet the circuit board contact springs. Alternatively, a battery contact or contacts in the bottom housing can enable the positive underside of the coin cell battery to be brought up to the negative top side to contact the circuit board. Venting layer **729** may be posi- (https://patentimages.storage.googleapis.com/0f/68/ad/d5456996abdaf3/US11589792B1.pdf)

<u>**Claim 10**</u>	<u>**Accused Instrumentalities**</u>
10. The wearable electrocardiography monitoring device of Claim 8, wherein the wireless transceiver is configured to communicate with an external device via Wi-Fi, mobile phone communication standards, or Bluetooth.	***The Accused Instrumentalities include the wearable electrocardiography monitoring device of Claim 8, wherein the wireless transceiver is configured to communicate with an external device via Wi-Fi, mobile phone communication standards, or Bluetooth.*** The Zio Monitor satisfies Claim 10 because the Zio Monitor includes a wireless transceiver that communicates with an external device, for example, via Bluetooth. *See* 8[o].

Claim 11	**Accused Instrumentalities**
11. The wearable electrocardiography monitoring device of Claim 8, wherein the electrocardiographic signals are converted to a different format.	***The Accused Instrumentalities include wherein the electrocardiographic signals are converted to a different format.*** The Zio Monitor satisfies Claim 11 because the Zio Monitor includes a processor that converts electrocardiographic signals to a different format. *See* 8[t]-8[u].

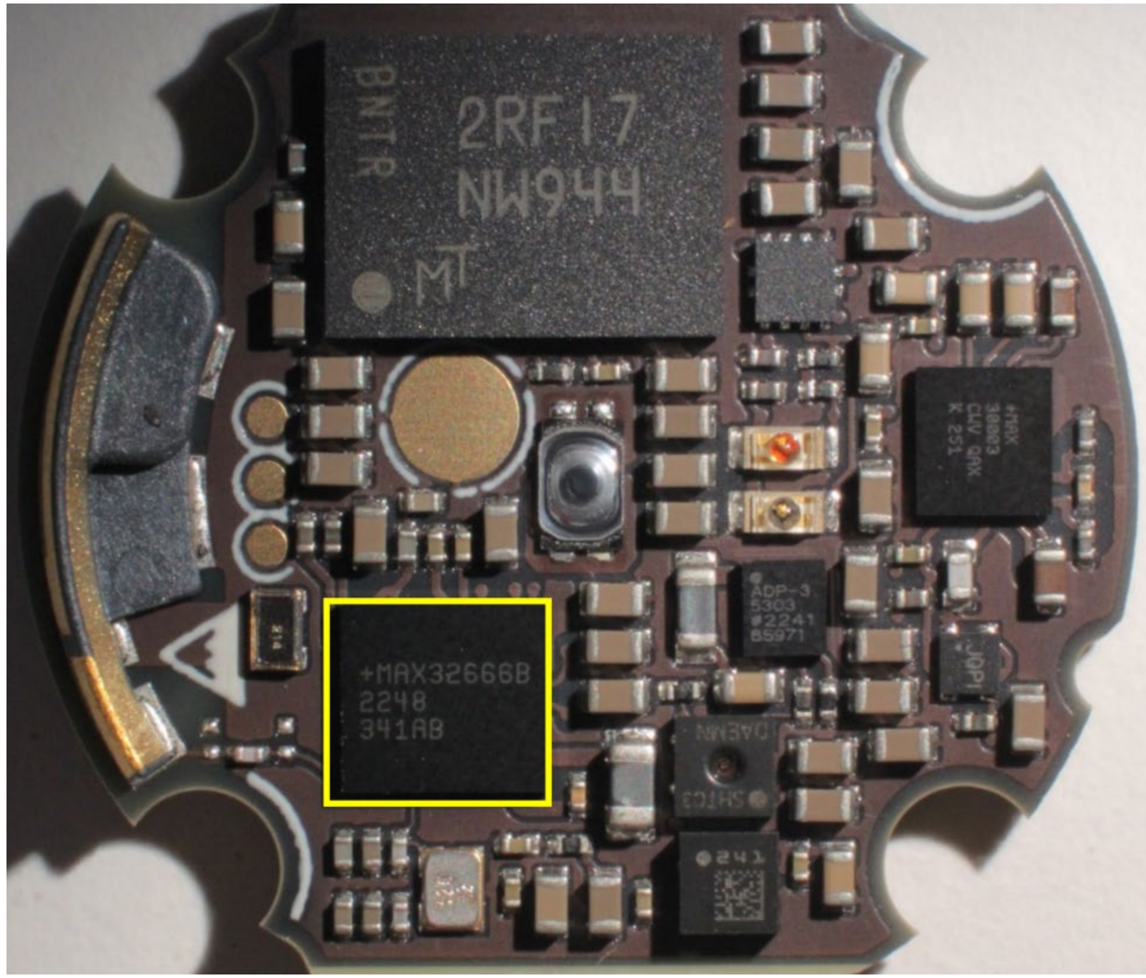
Claim 12	**Accused Instrumentalities**
12. The wearable electrocardiography monitoring device of Claim 11, wherein the electrocardiographic signals are retrieved by one of a server, a client computer, and a mobile device via the wireless transceiver after the electrocardiographic signals are converted to the different format.	***The Accused Instrumentalities include wearable electrocardiography monitoring device of Claim 11, wherein the electrocardiographic signals are retrieved by one of a server, a client computer, and a mobile device via the wireless transceiver after the electrocardiographic signals are converted to the different format.*** The Zio Monitor satisfies Claim 12 because the Zio Monitor includes a processor that converts electrocardiographic signals to a different format. *See* 8[t]-8[u].

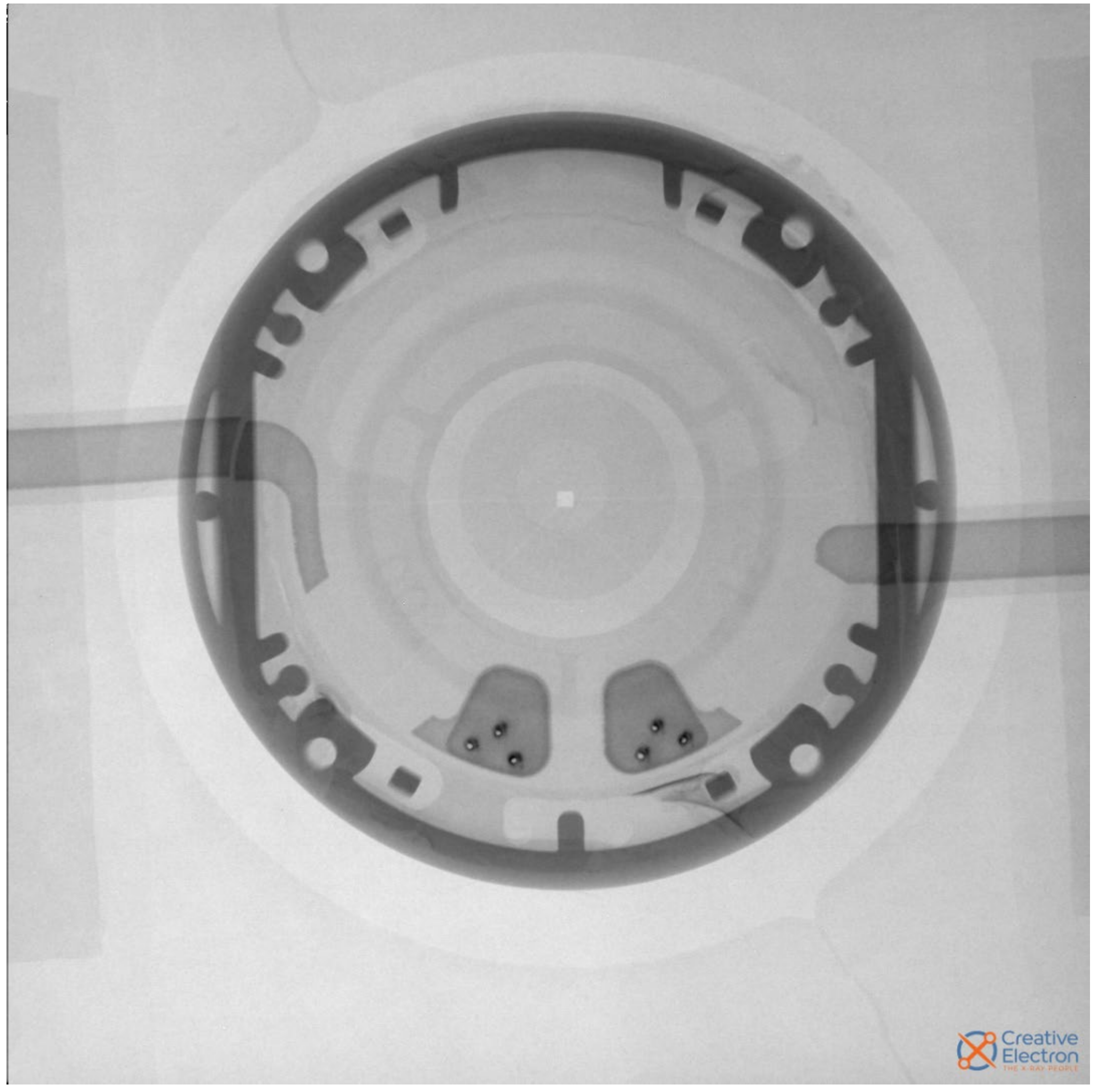
Claim 13	**Accused Instrumentalities**
13. The wearable electrocardiography monitoring device of	***The Accused Instrumentalities include the wearable electrocardiography monitoring device of Claim 8, wherein the adhesive covering the portion of the first face of the strip is provided on the first end section and the second end section only.*** The Zio Monitor satisfies Claim 13 because the

Claim 13	**Accused Instrumentalities**
Claim 8, wherein the adhesive covering the portion of the first face of the strip is provided on the first end section and the second end section only.	Zio Monitor includes an under side (i.e., a first face) and an upper side (i.e., a second face). *See* 8[b]. The Zio Monitor includes two wing portions that are covered in adhesive to adhere the strip to skin of a patient. *See id.* Further, the mid-section portion of the Zio Monitor is not covered in adhesive. *See id.*

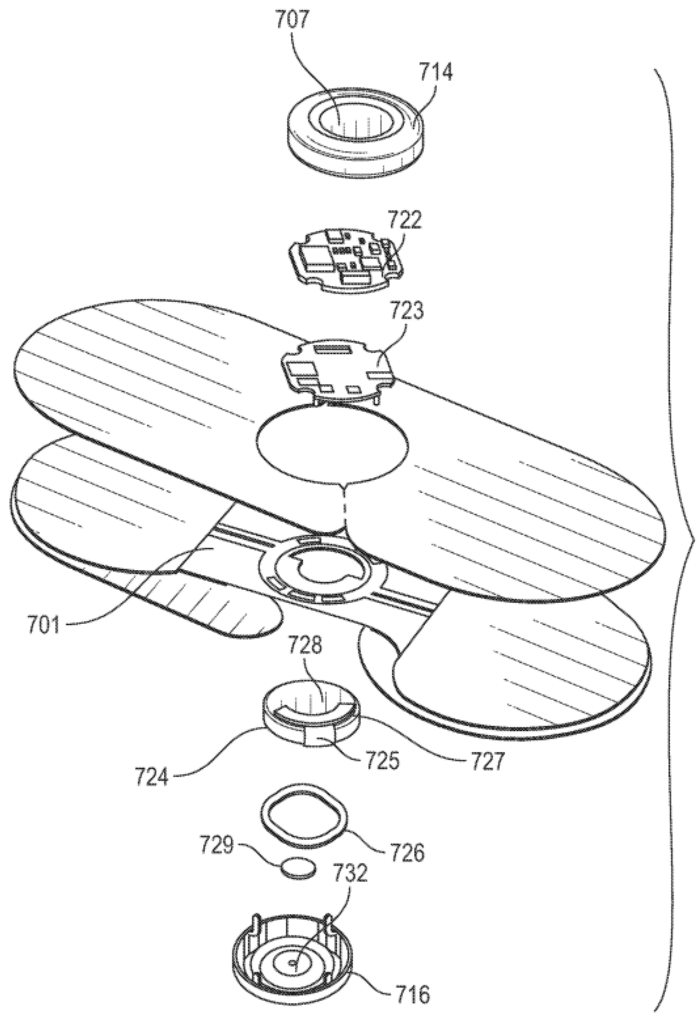
Claim 14	**Accused Instrumentalities**
14. The wearable electrocardiography monitoring device of Claim 8, wherein the battery is vertically aligned with the wireless transceiver.	***The Accused Instrumentalities include the wearable electrocardiography monitoring device of Claim 8, wherein the battery is vertically aligned with the wireless transceiver.*** The Zio Monitor satisfies Claim 14 because the Zio Monitor includes a battery that is vertically aligned with the wireless transceiver. *See* 8[n]; 9.  (Zio Monitor Teardown)

Claim 14	**Accused Instrumentalities**
	 (Zio Monitor Teardown)

Claim 14	Accused Instrumentalities
	 (Zio Monitor Teardown)

Claim 14	Accused Instrumentalities
	 (Zio Monitor Teardown)

Claim 14	**Accused Instrumentalities**
	This web page is provided to satisfy the virtual patent marking provisions of various jurisdictions including the virtual patent marking provisions of the America Invents Act and provide notice under 35 U.S.C. §287(a), that the iRhythm Technologies' Zio patch products and related services, including but not limited to the Zio patch, Zio XT, Zio AT, and Zio MCT trademarked products, are covered by or for use under one or more of the patents listed below. Zio patch products and related services are covered by or for use under one or more international patents or international patent applications. Zio patch products and related services not listed here may be protected by one or more patents in the United States and other international jurisdictions and may be covered by patents in the United States and other international jurisdictions that are not listed. iRhythm Technologies' Zio patch products and related services may be sold individually or as part of a combination product or system. US Patent Numbers*: 8,538,503; 8,560,046; 9,173,670; 9,241,649; 9,451,975; 9,597,004; 9,955,887; 10,098,559; 10,271,754; 10,299,691; D852965; D854167; 10,405,799; 10,517,500; 11,141,091; 10,555,683; 11,627,902; 11,051,738; 10,667,712; 10,813,565; 11,605,458; 11,289,197; 11,350,864; 11,350,865; 11,589,792; 11,337,632; 11,504,041; 11,246,523; 11,399,760; 11,246,524; 11,382,555; 11,083,371; 11,253,185; 11,253,186; 11,375,941 and 11,497,432. Additional patents are pending in the United States. (https://www.irhythmtech.com/content/patents-trademarks)

Claim 14	**Accused Instrumentalities**
	 FIG. 6H (https://patentimages.storage.googleapis.com/0f/68/ad/d5456996abdaf3/US11589792B1.pdf)

Claim 14	Accused Instrumentalities
	springs connected to the circuit board. Battery terminal **725**, may be positioned below the flexible body **701** and circuit boards **722**, thereby overlying wave spring **726**. In embodiments, the battery terminal **725** may be wrapped around and adhered to a coin cell battery **728**. The battery terminal **725** may be constructed as a flex circuit with conductive vias **727** that enables the positive underside of the coin cell battery **728** to be brought up to the negative top side of the battery, so that both the negative and positive terminals are presented on the top side of the battery to meet the circuit board contact springs. Alternatively, a battery contact or contacts in the bottom housing can enable the positive underside of the coin cell battery to be brought up to the negative top side to contact the circuit board. Venting layer **729** may be posi- (https://patentimages.storage.googleapis.com/0f/68/ad/d5456996abdaf3/US11589792B1.pdf)

Claim 15	**Accused Instrumentalities**
15[pre] A wearable electrocardiography monitoring device, comprising:	***To the extent the preamble is deemed to be a limitation, the Accused Instrumentalities include a wearable electrocardiography monitoring device in accordance with this claim.*** The Zio Monitor satisfies 15[pre] because the Zio Monitor is a device that is worn on the patient's body. *See* 8[pre]. In an example, the Zio Monitor monitors patient ECG signals. *See id.*
15[a] a flexible backing including a strip comprising:	***The Accused Instrumentalities include a flexible backing including a strip.*** The Zio Monitor satisfies 15[a] because the Zio Monitor includes a flexible backing including a strip. *See* 8[a].
15[b] a first face and a second face, wherein a portion of the first face is covered in adhesive to adhere the strip to skin of a patient,	***The Accused Instrumentalities include a first face and a second face, wherein a portion of the first face is covered in adhesive to adhere the strip to skin of a patient.*** The Zio Monitor satisfies 15[b] because the Zio Monitor includes an under side (i.e., a first face) and an upper side (i.e., a second face). *See* 8[b]. A portion of the under side is covered in adhesive to adhere the strip to skin of a patient. *See id.*
15[c] a first end section opposite a second end section, wherein a mid-section is disposed between the first end section and the second end section,	***The Accused Instrumentalities include a first end section opposite a second end section, wherein a mid-section is disposed between the first end section and the second end section.*** The Zio Monitor satisfies 15[c] because the Zio Monitor includes a first end section that is opposite a second end section. *See* 8[c]. The Zio Monitor also includes a mid-section between the first end section and the second end section. *See* 8[c].
15[d] wherein the mid-section is narrower than the first end section and the second end section, and wherein the mid-section includes a first edge parallel to a second edge; and	***The Accused Instrumentalities include wherein the mid-section is narrower than the first end section and the second end section, and wherein the mid-section includes a first edge parallel to a second edge.*** The Zio Monitor satisfies 15[d] because the Zio Monitor includes a mid-section that is narrower than each end section. *See* 8[d]. The mid-section has two edges (i.e., a first edge and a second edge) that are parallel to each other. *Id.*

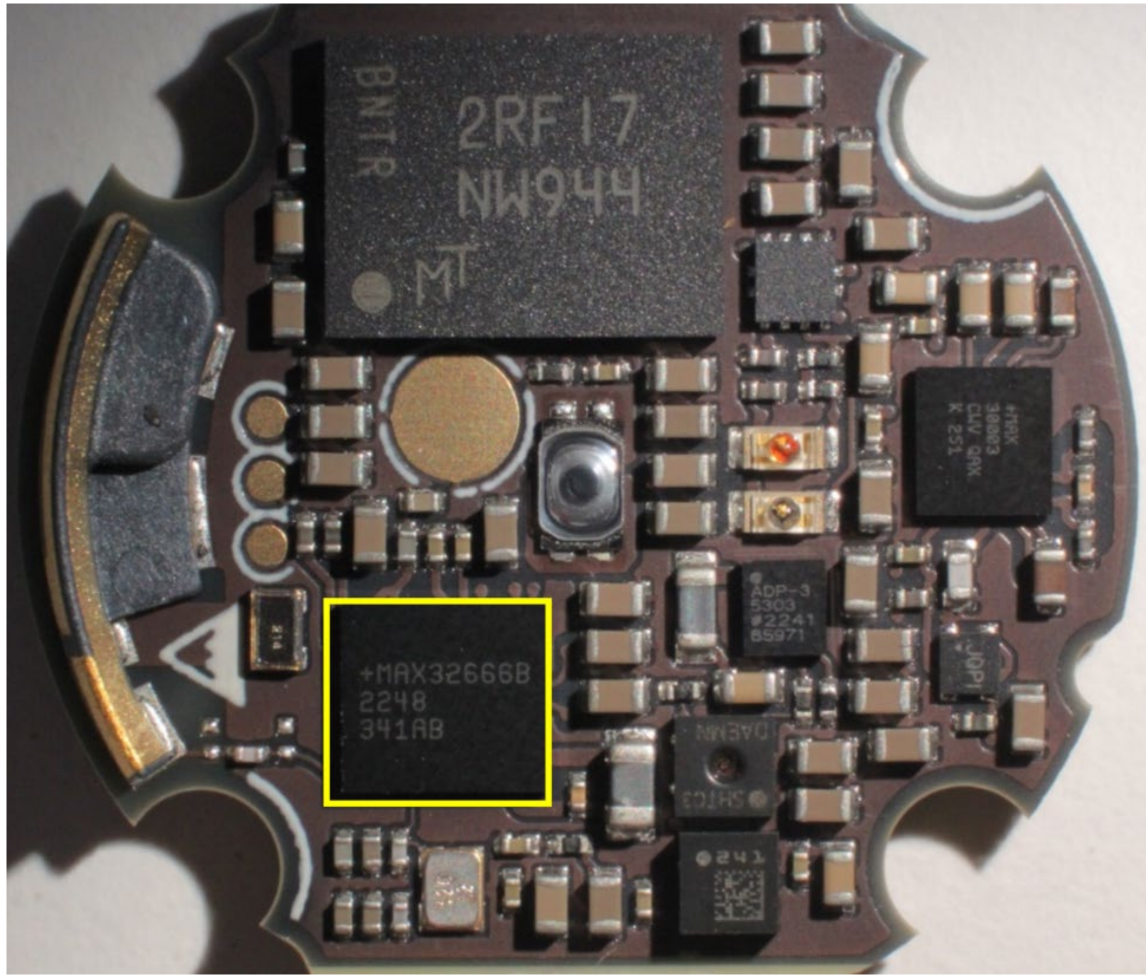
Claim 15	**Accused Instrumentalities**
15[e] a flexible circuit, wherein the flexible circuit comprises a first circuit trace and a second circuit trace on the second face of the flexible backing;	***The Accused Instrumentalities include a flexible circuit, wherein the flexible circuit comprises a first circuit trace and a second circuit trace on the second face of the flexible backing.*** The Zio Monitor satisfies 15[e] because the Zio Monitor includes a flexible circuit comprising two circuit traces (i.e., a first circuit trace and a second circuit trace). *See* 8[e]. The flexible circuit is mounted to the upper side of the strip (i.e., second face). *See id.*
15[f] a first electrocardiographic electrode configured to sense electrocardiographic signals,	***The Accused Instrumentalities include a first electrocardiographic electrode configured to sense electrocardiographic signals.*** The Zio Monitor satisfies 15[f] because the Zio Monitor includes two electrocardiographic electrode (i.e., a first electrocardiographic electrode and a second electrocardiographic electrode). *See* 8[f]-8[g]. The first electrocardiographic electrode senses electrocardiographic signals. *See* 8[f]-8[g].
15[g] wherein the first electrocardiographic electrode is conductively exposed at the first face along the second end section of the flexible backing, and	***The Accused Instrumentalities include wherein the first electrocardiographic electrode is conductively exposed at the first face along the second end section of the flexible backing.*** The Zio Monitor satisfies 15[g] because the Zio Monitor includes an electrocardiographic electrode (i.e., the first electrocardiographic electrode) conductively exposed on the upper side (i.e., the first face) along one end (i.e., the second end section) of the strip. *See* 8[i].
15[h] wherein the first electrocardiographic electrode is electrically coupled to the first circuit trace;	***The Accused Instrumentalities include wherein the first electrocardiographic electrode is electrically coupled to the first circuit trace.*** The Zio Monitor satisfies 15[h] because the Zio Monitor includes circuit traces, one of which (i.e., the first circuit trace) is electrically coupled to one of the electrocardiographic electrodes (i.e., the first electrocardiographic electrode). *See* 8[k].
15[i] a second electrocardiographic electrode configured to sense electrocardiographic signals,	***The Accused Instrumentalities include a second electrocardiographic electrode configured to sense electrocardiographic signals.*** The Zio Monitor satisfies 15[i] because the Zio Monitor includes two electrocardiographic electrode (i.e., a first electrocardiographic electrode and a second electrocardiographic electrode). *See* 8[f]-8[g]. The second electrocardiographic electrode senses electrocardiographic signals. *See* 8[f]-8[g]; 15[f].

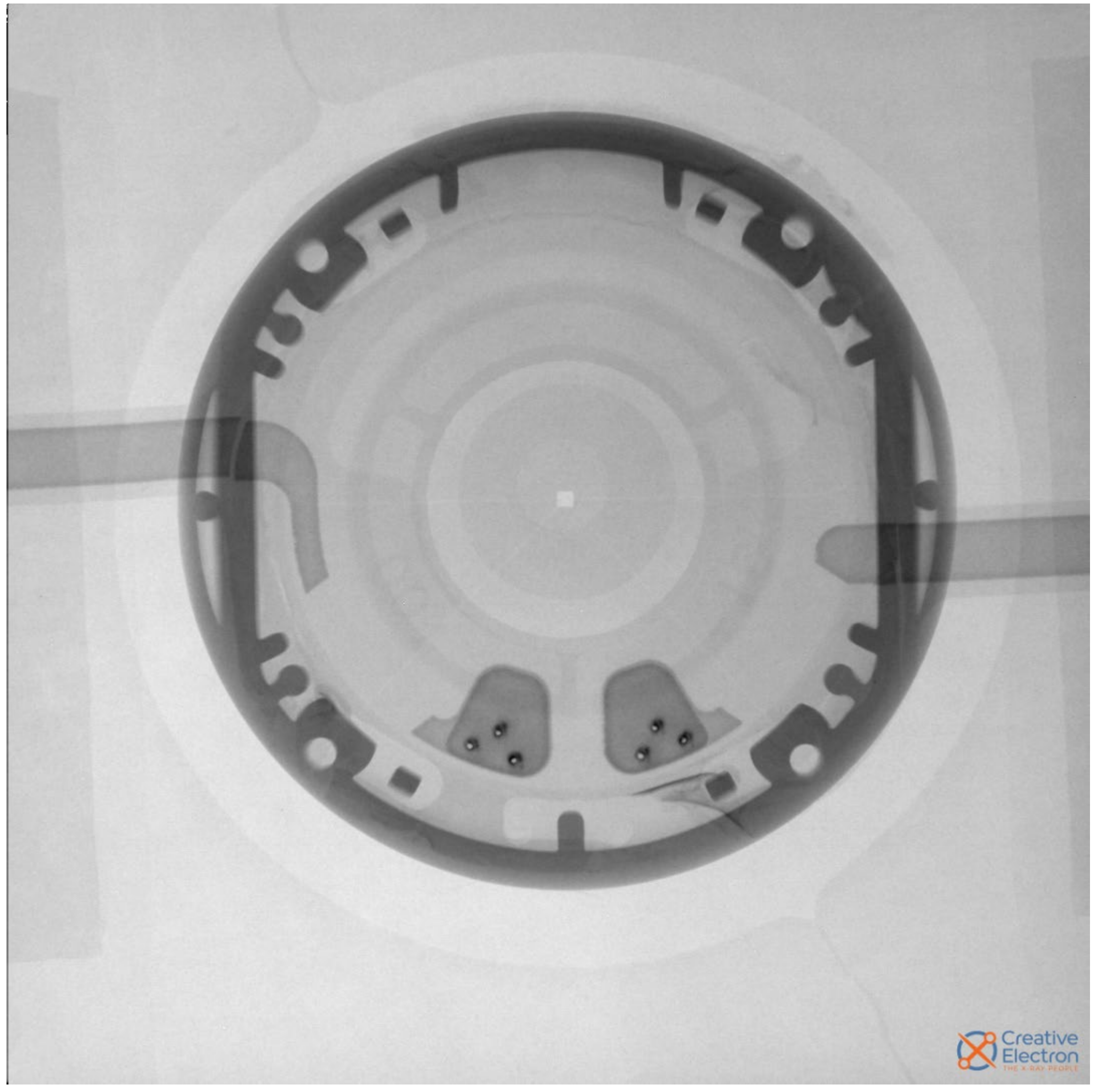
Claim 15	Accused Instrumentalities
15[j] wherein the second electrocardiographic electrode is conductively exposed at the first face along the first end section of the flexible backing,	***The Accused Instrumentalities include wherein the second electrocardiographic electrode is conductively exposed at the first face along the first end section of the flexible backing.*** The Zio Monitor satisfies 15[j] because the Zio Monitor includes an electrocardiographic electrode (i.e., the second electrocardiographic electrode) conductively exposed on the upper side (i.e., the first face) along one end (i.e., the first end section) of the strip. *See* 8[j].
15[k] and wherein the second electrocardiographic electrode is electrically coupled to the second circuit trace;	***The Accused Instrumentalities include wherein the second electrocardiographic electrode is electrically coupled to the second circuit trace.*** The Zio Monitor satisfies 15[k] because the Zio Monitor includes circuit traces, one of which (i.e., the first circuit trace) is electrically coupled to one of the electrocardiographic electrodes (i.e., the first electrocardiographic electrode). *See* 8[k].
15[l] a sealed housing having rounded edges on a top surface,	***The Accused Instrumentalities include a sealed housing having rounded edges on a top surface.*** The Zio Monitor satisfies 15[l] because the Zio Monitor includes a sealed housing with rounded edges on its top surface. *See* 8[q].
15[m] wherein the sealed housing is coupled to the flexible backing,	***The Accused Instrumentalities include a sealed housing wherein the sealed housing is coupled to the flexible backing.*** The Zio Monitor satisfies 15[m] because the Zio Monitor includes a sealed housing that is coupled to the flexible backing. *See* 8[r].
15[n] wherein the sealed housing includes a processor, wherein the processor is electrically coupled to the first electrocardiographic electrode and the second electrocardiographic electrode,	***The Accused Instrumentalities include a sealed housing wherein the sealed housing includes a processor, wherein the processor is electrically coupled to the first electrocardiographic electrode and the second electrocardiographic electrode.*** The Zio Monitor satisfies 15[n] because the Zio Monitor has a processer in its sealed housing. *See* 8[s]-8[t].
15[o] wherein the processor is configured to	***The Accused Instrumentalities include a processor wherein the processor is configured to process the electrocardiographic signals sensed via the first electrocardiographic electrode and the second***

Claim 15	**Accused Instrumentalities**
process the electrocardiographic signals sensed via the first electrocardiographic electrode and the second electrocardiographic electrode;	***electrocardiographic electrode.*** The Zio Monitor satisfies 15[o] because the Zio Monitor's processor processes electrocardiographic signals sensed by its electrocardiographic electrodes. *See* 8[u].
15[p] a button disposed on the top surface of the sealed housing, wherein the button is configured to be pressed to mark an event;	***The Accused Instrumentalities include a button disposed on the top surface of the sealed housing, wherein the button is configured to be pressed to mark an event.*** The Zio Monitor satisfies 15[p] because the Zio Monitor includes a button configured to be pressed by a patient when a symptom (i.e., an event) occurs. *See* 8[p]. The button is located on the top of the sealed housing. *See id.*
15[q] a battery disposed between the processor and the skin of the patient, the battery configured to provide power to the processor of the sealed housing; and	***The Accused Instrumentalities include a battery disposed between the processor and the skin of the patient, the battery configured to provide power to the processor of the sealed housing.*** The Zio Monitor satisfies 15[q] because the Zio Monitor includes a battery. *See* 8[n]; 9; 14. The battery powers the body worn device. *See* 8[n]; 9; 14. The battery is located between the processor and the skin of the patient. *See* 8[n]; 9; 14.

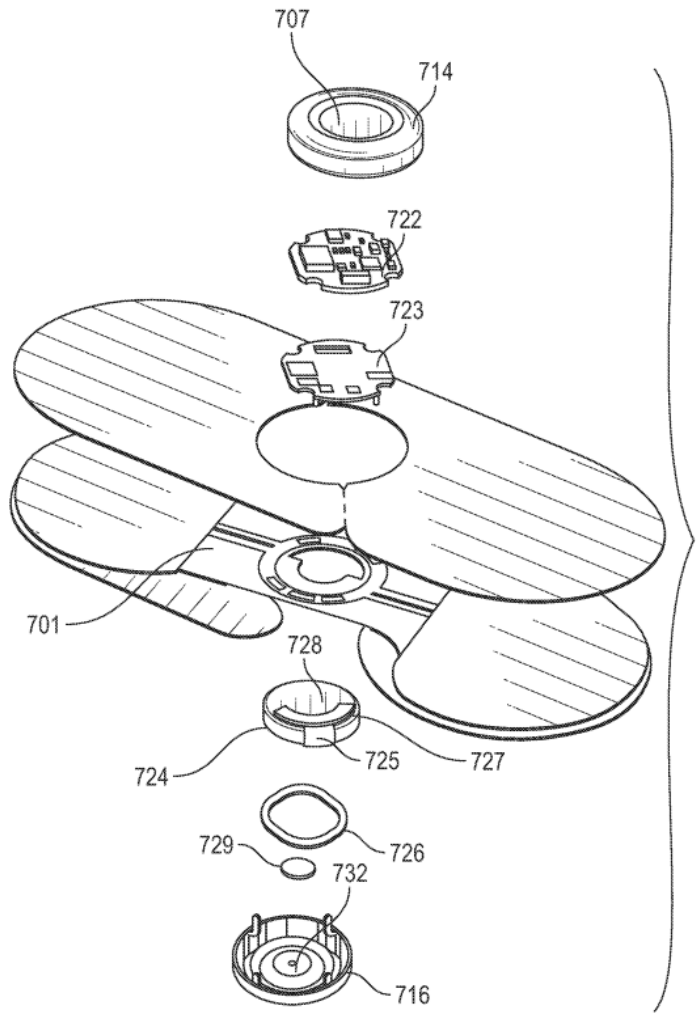
Claim 15	**Accused Instrumentalities**
	 (Zio Monitor Teardown)  (Zio Monitor Teardown)

321819903.2

Claim 15	Accused Instrumentalities
	 (Zio Monitor Teardown)

Claim 15	**Accused Instrumentalities**
	 (Zio Monitor Teardown)

Claim 15	Accused Instrumentalities
	This web page is provided to satisfy the virtual patent marking provisions of various jurisdictions including the virtual patent marking provisions of the America Invents Act and provide notice under 35 U.S.C. §287(a), that the iRhythm Technologies' Zio patch products and related services, including but not limited to the Zio patch, Zio XT, Zio AT, and Zio MCT trademarked products, are covered by or for use under one or more of the patents listed below. Zio patch products and related services are covered by or for use under one or more international patents or international patent applications. Zio patch products and related services not listed here may be protected by one or more patents in the United States and other international jurisdictions and may be covered by patents in the United States and other international jurisdictions that are not listed. iRhythm Technologies' Zio patch products and related services may be sold individually or as part of a combination product or system. US Patent Numbers*: 8,538,503; 8,560,046; 9,173,670; 9,241,649; 9,451,975; 9,597,004; 9,955,887; 10,098,559; 10,271,754; 10,299,691; D852965; D854167; 10,405,799; 10,517,500; 11,141,091; 10,555,683; 11,627,902; 11,051,738; 10,667,712; 10,813,565; 11,605,458; 11,289,197; 11,350,864; 11,350,865; 11,589,792; 11,337,632; 11,504,041; 11,246,523; 11,399,760; 11,246,524; 11,382,555; 11,083,371; 11,253,185; 11,253,186; 11,375,941 and 11,497,432. Additional patents are pending in the United States. (https://www.irhythmtech.com/content/patents-trademarks)

Claim 15	Accused Instrumentalities
	 FIG. 6H (https://patentimages.storage.googleapis.com/0f/68/ad/d5456996abdaf3/US11589792B1.pdf)

Claim 15	Accused Instrumentalities
	springs connected to the circuit board. Battery terminal **725**, may be positioned below the flexible body **701** and circuit boards **722**, thereby overlying wave spring **726**. In embodiments, the battery terminal **725** may be wrapped around and adhered to a coin cell battery **728**. The battery terminal **725** may be constructed as a flex circuit with conductive vias **727** that enables the positive underside of the coin cell battery **728** to be brought up to the negative top side of the battery, so that both the negative and positive terminals are presented on the top side of the battery to meet the circuit board contact springs. Alternatively, a battery contact or contacts in the bottom housing can enable the positive underside of the coin cell battery to be brought up to the negative top side to contact the circuit board. Venting layer **729** may be posi- (https://patentimages.storage.googleapis.com/0f/68/ad/d5456996abdaf3/US11589792B1.pdf)

Claim 15	Accused Instrumentalities
15[r] a wireless transceiver configured to communicate at least a portion of the electrocardiographic signals.	***The Accused Instrumentalities include a wireless transceiver configured to communicate at least a portion of the electrocardiographic signals.*** The Zio Monitor satisfies 15[r] because the Zio Monitor includes a wireless transceiver. *See* 8[o]. The wireless transceiver is configured to communicate electrocardiographic signals. *Id.*

Claim 16	Accused Instrumentalities
16. The wearable electrocardiography monitoring device of Claim 15, wherein the wireless transceiver is configured to communicate with an external device via Wi-Fi, mobile phone communication standards, or Bluetooth.	***The Accused Instrumentalities includes the wearable electrocardiography monitoring device of Claim 15, wherein the wireless transceiver is configured to communicate with an external device via Wi-Fi, mobile phone communication standards, or Bluetooth.*** The Zio Monitor satisfies Claim 16 because the Zio Monitor includes a wireless transceiver that communicates with an external device, for example, via Bluetooth. *See* 8[o]; 15[r].

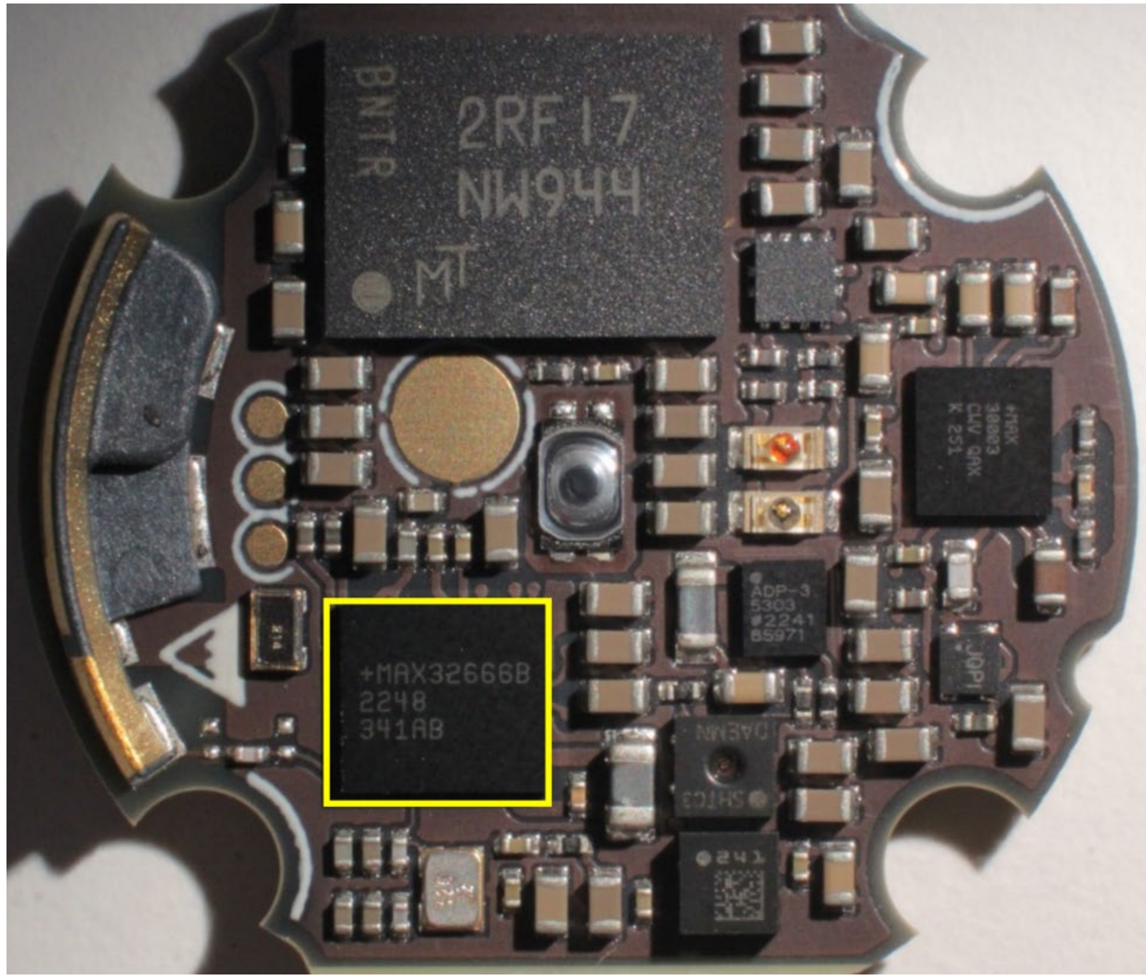
Claim 17	Accused Instrumentalities
17. The wearable electrocardiography monitoring device of Claim 15, wherein the electrocardiographic signals are converted to a different format.	***The Accused Instrumentalities includes the wearable electrocardiography monitoring device of Claim 15, wherein the electrocardiographic signals are converted to a different format.*** The Zio Monitor satisfies Claim 17 because the Zio Monitor includes a processor that converts electrocardiographic signals to a different format. *See* 8[t]-8[u].

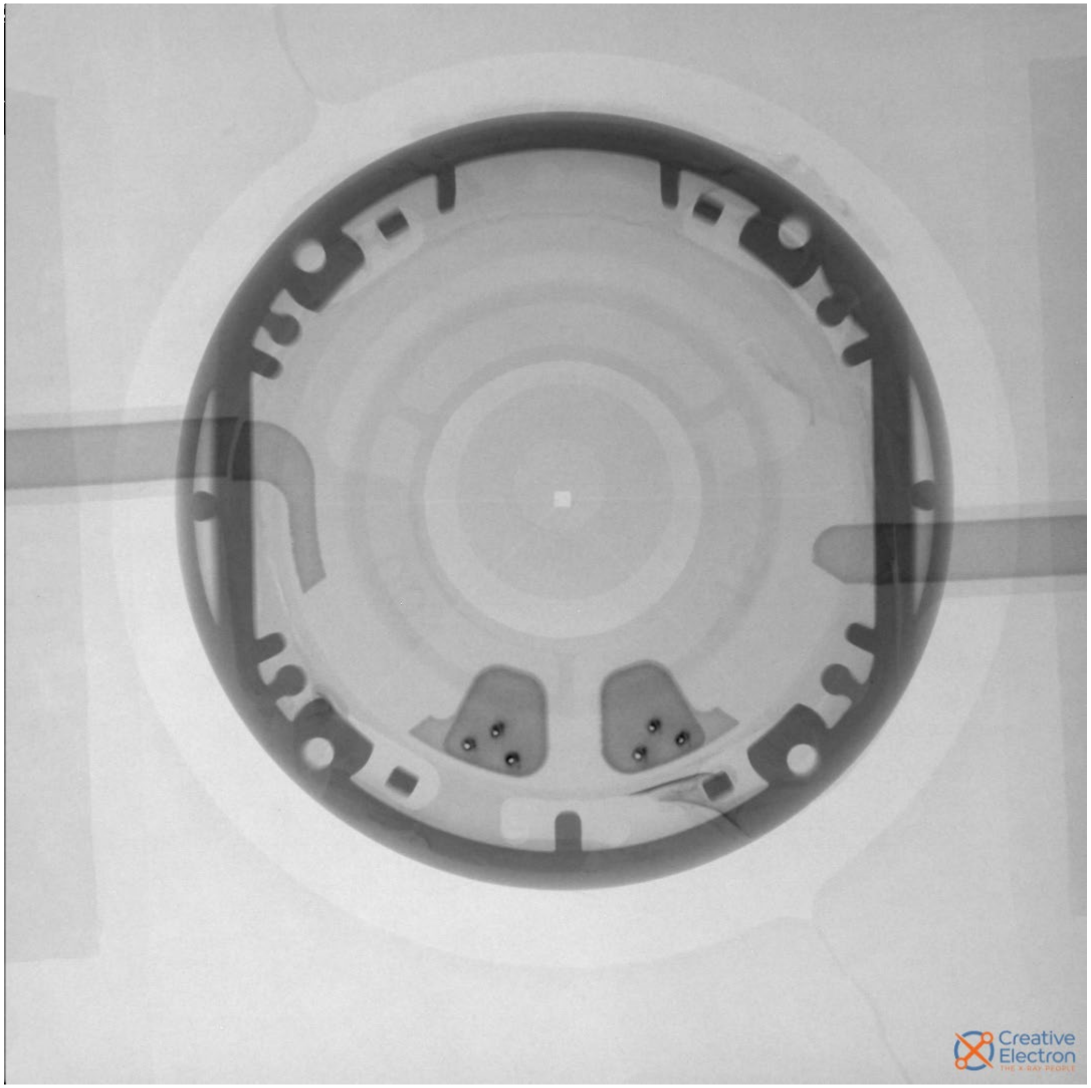
Claim 18	Accused Instrumentalities
18. The wearable electrocardiography monitoring device of Claim 17, wherein the electrocardiographic signals are retrieved by one of a server, a client computer, and a mobile device via the wireless transceiver after the electrocardiographic signals are converted to the different format.	***The Accused Instrumentalities includes the wearable electrocardiography monitoring device of Claim 17, wherein the electrocardiographic signals are retrieved by one of a server, a client computer, and a mobile device via the wireless transceiver after the electrocardiographic signals are converted to the different format.*** The Zio Monitor satisfies Claim 18 because the Zio Monitor includes a wireless transceiver that communicates with an external device, for example, via Bluetooth. *See* 8[o], 8[t]-8[u]. After the electrocardiographic signals are converted to a different format via the processor, (*see* 8[t]-8[u]), the electrocardiographic signals are received by one of a server, a client computer, and a mobile device. Welcome to Zio monitor **Product Description** The Zio® ECG Monitoring System is an ambulatory Electrocardiogram (ECG) monitoring system. The Zio ECG Monitoring System consists of two components: (1) Zio monitor (2) proprietary algorithm software. The Zio monitor is a single-use ECG monitor that provides a continuous, single-channel recording for up to 14 days. The Zio monitor records ECG data without patient interaction, with the goal of improving patient compliance via simplicity of operation. Patients have the option of pressing a convenient button and filling out a log to document symptomatic events, which will support symptom-rhythm correlation in the diagnostic report. After conclusion of the wear period (up to 14 days), the patient removes the Zio monitor and returns it by mail to iRhythm for processing. After receipt, the data is analyzed by iRhythm's proprietary algorithm before a Certified Cardiographic Technician (CCT) reviews the results and generates a report of the key findings. (https://go.irhythmtech.com/hubfs/LB10117.01%20-%20ZIO%20MONITOR%20INSTRUCTIONS%20FOR%20USE%2c%20PRINTED%20(2).pdf)

Claim 19	Accused Instrumentalities
19. The wearable electrocardiography monitoring device of Claim 15, wherein the adhesive covering the portion of the first face is provided on the first end section and the second end section only.	***The Accused Instrumentalities include the wearable electrocardiography monitoring device of Claim 15, wherein the adhesive covering the portion of the first face of the strip is provided on the first end section and the second end section only.*** The Zio Monitor satisfies Claim 19 because the Zio Monitor includes an under side (i.e., a first face) and an upper side (i.e., a second face). *See* 8[b]; 15[b]. The Zio Monitor includes two wing portions that are covered in adhesive to adhere the strip to skin of a patient. *See* 8[b]; 15[b]. Further, the mid-section portion of the Zio Monitor is not covered in adhesive. *See* 8[b]; 15[b].

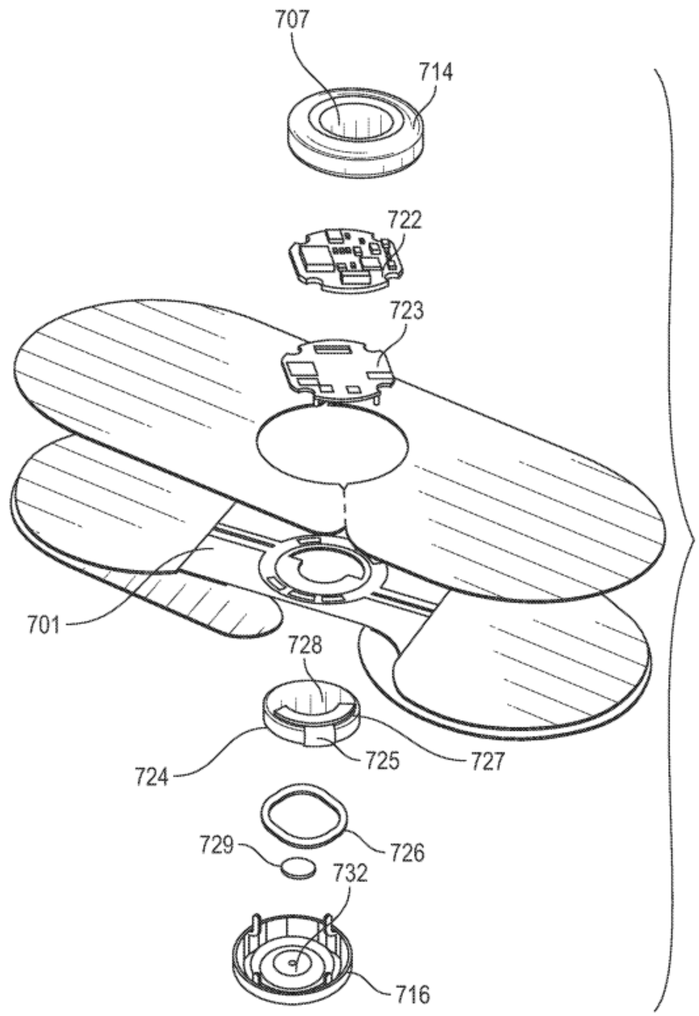
Claim 20	Accused Instrumentalities
20. The wearable electrocardiography monitoring device of Claim 15, wherein the battery is vertically aligned with the wireless transceiver.	***The Accused Instrumentalities include the wearable electrocardiography monitoring device of Claim 15, wherein the battery is vertically aligned with the wireless transceiver.*** The Zio Monitor satisfies Claim 20 because the Zio Monitor includes a battery that is vertically aligned with the wireless transceiver. *See* 8[n]; 9; 14; 15[q].

Claim 20	**Accused Instrumentalities**
	 (Zio Monitor Teardown)  (Zio Monitor Teardown)

Claim 20	Accused Instrumentalities
	 (Zio Monitor Teardown)

Claim 20	**Accused Instrumentalities**
	 (Zio Monitor Teardown)

Claim 20	Accused Instrumentalities
	This web page is provided to satisfy the virtual patent marking provisions of various jurisdictions including the virtual patent marking provisions of the America Invents Act and provide notice under 35 U.S.C. §287(a), that the iRhythm Technologies' Zio patch products and related services, including but not limited to the Zio patch, Zio XT, Zio AT, and Zio MCT trademarked products, are covered by or for use under one or more of the patents listed below. Zio patch products and related services are covered by or for use under one or more international patents or international patent applications. Zio patch products and related services not listed here may be protected by one or more patents in the United States and other international jurisdictions and may be covered by patents in the United States and other international jurisdictions that are not listed. iRhythm Technologies' Zio patch products and related services may be sold individually or as part of a combination product or system. US Patent Numbers*: 8,538,503; 8,560,046; 9,173,670; 9,241,649; 9,451,975; 9,597,004; 9,955,887; 10,098,559; 10,271,754; 10,299,691; D852965; D854167; 10,405,799; 10,517,500; 11,141,091; 10,555,683; 11,627,902; 11,051,738; 10,667,712; 10,813,565; 11,605,458; 11,289,197; 11,350,864; 11,350,865; 11,589,792; 11,337,632; 11,504,041; 11,246,523; 11,399,760; 11,246,524; 11,382,555; 11,083,371; 11,253,185; 11,253,186; 11,375,941 and 11,497,432. Additional patents are pending in the United States. (https://www.irhythmtech.com/content/patents-trademarks)

Claim 20	Accused Instrumentalities
	 FIG. 6H (https://patentimages.storage.googleapis.com/0f/68/ad/d5456996abdaf3/US11589792B1.pdf)

Claim 20	Accused Instrumentalities
	springs connected to the circuit board. Battery terminal **725**, may be positioned below the flexible body **701** and circuit boards **722**, thereby overlying wave spring **726**. In embodiments, the battery terminal **725** may be wrapped around and adhered to a coin cell battery **728**. The battery terminal **725** may be constructed as a flex circuit with conductive vias **727** that enables the positive underside of the coin cell battery **728** to be brought up to the negative top side of the battery, so that both the negative and positive terminals are presented on the top side of the battery to meet the circuit board contact springs. Alternatively, a battery contact or contacts in the bottom housing can enable the positive underside of the coin cell battery to be brought up to the negative top side to contact the circuit board. Venting layer **729** may be posi- (https://patentimages.storage.googleapis.com/0f/68/ad/d5456996abdaf3/US11589792B1.pdf)

<u>**Claim 21**</u>	<u>**Accused Instrumentalities**</u>
21[pre] The wearable electrocardiography monitoring device of Claim 15,	***The Accused Instrumentalities include the wearable electrocardiography monitoring device of Claim 15.*** The Zio Monitor satisfies Claim 15. *See, e.g.*, 15[pre].
21[a] wherein the wireless transceiver is configured to communicate with an external device via Wi-Fi, mobile phone communication standards, or Bluetooth,	***The Accused Instrumentalities includes the wearable electrocardiography monitoring device of Claim 15, wherein the wireless transceiver is configured to communicate with an external device via Wi-Fi, mobile phone communication standards, or Bluetooth.*** The Zio Monitor satisfies Claim 21[a] because the Zio Monitor includes a wireless transceiver that communicates with an external device, for example, via Bluetooth. *See* 8[o]; 15[r]; 16.
21[b] wherein the electrocardiographic signals are converted to a different format,	***The Accused Instrumentalities includes the wearable electrocardiography monitoring device of Claim 15, wherein the electrocardiographic signals are converted to a different format.*** The Zio Monitor satisfies Claim 21[b] because the Zio Monitor includes a processor that converts electrocardiographic signals to a different format. *See* 8[t]-8[u]; 15[n]-15[o].
21[c] wherein the electrocardiographic signals are retrieved by one of a server, a client computer, and a mobile device via the wireless transceiver after the electrocardiographic signals are converted to the different format,	***The Accused Instrumentalities includes the wearable electrocardiography monitoring device of Claim 15, wherein the electrocardiographic signals are retrieved by one of a server, a client computer, and a mobile device via the wireless transceiver after the electrocardiographic signals are converted to the different format.*** The Zio Monitor satisfies Claim 21[c] because the Zio Monitor includes a wireless transceiver that communicates with an external device, for example, via Bluetooth. *See* 8[o], 8[t]-8[u]; 16. After the electrocardiographic signals are converted to a different format via the processor, *see* 8[t]-8[u]; 16, the electrocardiographic signals are received by one of a server, a client computer, and a mobile device.
21[d] wherein the adhesive covering the portion of the first face is provided on the first end section and the	***The Accused Instrumentalities include the wearable electrocardiography monitoring device of Claim 15, wherein the adhesive covering the portion of the first face of the strip is provided on the first end section and the second end section only.*** The Zio Monitor satisfies Claim 21[d] because the Zio Monitor includes an under side (i.e., a first face) and an upper side (i.e., a second face). *See* 8[b];

Claim 21	**Accused Instrumentalities**
second end section only, and	15[b]; 19. The Zio Monitor includes two wing portions that are covered in adhesive to adhere the strip to skin of a patient. *See* 8[b]; 15[b]; 19. Further, the mid-section portion of the Zio Monitor is not covered in adhesive. *See* 8[b]; 15[b]; 19.
21[e] wherein the battery is vertically aligned with the wireless transceiver.	***The Accused Instrumentalities include the wearable electrocardiography monitoring device of Claim 15, wherein the battery is vertically aligned with the wireless transceiver.*** The Zio Monitor satisfies Claim 21[e] because the Zio Monitor includes a battery that is vertically aligned with the wireless transceiver. *See* 15[q]; 20.

Claim 22	**Accused Instrumentalities**
22[pre] The wearable electrocardiography monitoring device of Claim 15,	***The Accused Instrumentalities include the wearable electrocardiography monitoring device of Claim 15.*** The Zio Monitor satisfies Claim 22[pre]. *See* 21[pre]
22[a] wherein the wireless transceiver is configured to communicate with an external device via Wi-Fi, mobile phone communication standards, or Bluetooth,	***The Accused Instrumentalities includes the wearable electrocardiography monitoring device of Claim 15, wherein the wireless transceiver is configured to communicate with an external device via Wi-Fi, mobile phone communication standards, or Bluetooth.*** The Zio Monitor satisfies Claim 22[a]. *See* 21[a].
22[b] wherein the electrocardiographic signals are retrieved by one of a server, a client computer, and a mobile device via the wireless transceiver after the	***The Accused Instrumentalities includes the wearable electrocardiography monitoring device of Claim 15, wherein the electrocardiographic signals are retrieved by one of a server, a client computer, and a mobile device via the wireless transceiver after the electrocardiographic signals are converted to the different format.*** The Zio Monitor satisfies Claim 22[b]. *See* 21[c].

<u>**Claim 22**</u>	<u>**Accused Instrumentalities**</u>
electrocardiographic signals are converted to a different format,	
22[c] wherein the adhesive covering the portion of the first face is provided on the first end section and the second end section only, and	***The Accused Instrumentalities include the wearable electrocardiography monitoring device of Claim 15, wherein the adhesive covering the portion of the first face of the strip is provided on the first end section and the second end section only.*** The Zio Monitor satisfies Claim 22[c]. *See* 21[d].
22[d] wherein the battery is vertically aligned with the wireless transceiver.	***The Accused Instrumentalities include the wearable electrocardiography monitoring device of Claim 15, wherein the battery is vertically aligned with the wireless transceiver.*** The Zio Monitor satisfies Claim 22[d]. *See* 21[e].

<u>**Claim 23**</u>	<u>**Accused Instrumentalities**</u>
23[pre] The wearable electrocardiography monitoring device of Claim 15,	***The Accused Instrumentalities include the wearable electrocardiography monitoring device of Claim 15.*** The Zio Monitor satisfies Claim 23[pre]. *See* 21[pre].
23[a] wherein the wireless transceiver is configured to communicate with an external device via Wi-Fi, mobile phone communication standards, or Bluetooth,	***The Accused Instrumentalities includes the wearable electrocardiography monitoring device of Claim 15, wherein the wireless transceiver is configured to communicate with an external device via Wi-Fi, mobile phone communication standards, or Bluetooth.*** The Zio Monitor satisfies Claim 23[a]. *See* 21[a].

Claim 23	**Accused Instrumentalities**
23[b] wherein the electrocardiographic signals are converted to a different format,	***The Accused Instrumentalities include the wearable electrocardiography monitoring device of Claim 15, wherein the electrocardiographic signals are converted to a different format.*** The Zio Monitor satisfies Claim 23[b]. *See* 21[b].
23[c] wherein the adhesive covering the portion of the first face is provided on the first end section and the second end section only, and	***The Accused Instrumentalities include the wearable electrocardiography monitoring device of Claim 15, wherein the adhesive covering the portion of the first face of the strip is provided on the first end section and the second end section only.*** The Zio Monitor satisfies Claim 23[c]. *See* 21[d].
23[d] wherein the battery is vertically aligned with the wireless transceiver.	***The Accused Instrumentalities include the wearable electrocardiography monitoring device of Claim 15, wherein the battery is vertically aligned with the wireless transceiver.*** The Zio Monitor satisfies Claim 23[d]. *See* 21[e].

Claim 24	**Accused Instrumentalities**
24. The wearable electrocardiography monitoring device of Claim 15,	***The Accused Instrumentalities include the wearable electrocardiography monitoring device of Claim 15.*** The Zio Monitor satisfies Claim 24[pre]. *See* 21[pre].
24[a] wherein the wireless transceiver is configured to communicate with an external device via Wi-Fi, mobile phone communication standards, or Bluetooth,	***The Accused Instrumentalities includes the wearable electrocardiography monitoring device of Claim 15, wherein the wireless transceiver is configured to communicate with an external device via Wi-Fi, mobile phone communication standards, or Bluetooth.*** The Zio Monitor satisfies Claim 24[a]. *See* 21[a].

Claim 24	**Accused Instrumentalities**
24[b] wherein the electrocardiographic signals are converted to a different format,	***The Accused Instrumentalities include the wearable electrocardiography monitoring device of Claim 15, wherein the electrocardiographic signals are converted to a different format.*** The Zio Monitor satisfies Claim 24[b]. *See* 21[b].
24[c] wherein the electrocardiographic signals are retrieved by one of a server, a client computer, and a mobile device via the wireless transceiver after the electrocardiographic signals are converted to the different format, and	***The Accused Instrumentalities includes the wearable electrocardiography monitoring device of Claim 15, wherein the electrocardiographic signals are retrieved by one of a server, a client computer, and a mobile device via the wireless transceiver after the electrocardiographic signals are converted to the different format.*** The Zio Monitor satisfies Claim 24[c]. *See* 21[c].
24[d] wherein the battery is vertically aligned with the wireless transceiver.	***The Accused Instrumentalities include the wearable electrocardiography monitoring device of Claim 15, wherein the battery is vertically aligned with the wireless transceiver.*** The Zio Monitor satisfies Claim 24[d]. *See* 21[e].

Claim 25	**Accused Instrumentalities**
25[pre]. The wearable electrocardiography monitoring device of Claim 15,	***The Accused Instrumentalities include the wearable electrocardiography monitoring device of Claim 15.*** The Zio Monitor satisfies Claim 25[pre]. *See* 21[pre].
25[a] wherein the wireless transceiver is configured to communicate with an external device via Wi-Fi,	***The Accused Instrumentalities includes the wearable electrocardiography monitoring device of Claim 15, wherein the wireless transceiver is configured to communicate with an external device via Wi-Fi, mobile phone communication standards, or Bluetooth.*** The Zio Monitor satisfies Claim 25[a]. *See* 21[a].

Claim 25	Accused Instrumentalities
mobile phone communication standards, or Bluetooth,	
25[b] wherein the electrocardiographic signals are converted to a different format,	***The Accused Instrumentalities include the wearable electrocardiography monitoring device of Claim 15, wherein the electrocardiographic signals are converted to a different format.*** The Zio Monitor satisfies Claim 25[b]. *See* 21[b].
25[c] wherein the electrocardiographic signals are retrieved by one of a server, a client computer, and a mobile device via the wireless transceiver after the electrocardiographic signals are converted to the different format, and	***The Accused Instrumentalities includes the wearable electrocardiography monitoring device of Claim 15, wherein the electrocardiographic signals are retrieved by one of a server, a client computer, and a mobile device via the wireless transceiver after the electrocardiographic signals are converted to the different format.*** The Zio Monitor satisfies Claim 25[c]. *See* 21[c].
25[d] wherein the adhesive covering the portion of the first face is provided on the first end section and the second end section only.	***The Accused Instrumentalities include the wearable electrocardiography monitoring device of Claim 15, wherein the adhesive covering the portion of the first face of the strip is provided on the first end section and the second end section only.*** The Zio Monitor satisfies Claim 25[d]. *See* 21d].

Claim 26	Accused Instrumentalities
26[pre] The wearable electrocardiography	***The Accused Instrumentalities include the wearable electrocardiography monitoring device of Claim 15.*** The Zio Monitor satisfies Claim 26[pre]. *See* 21[pre].

Claim 26	**Accused Instrumentalities**
monitoring device of Claim 15,	
26[a] wherein the wireless transceiver is configured to communicate with an external device via Wi-Fi, mobile phone communication standards, or Bluetooth,	***The Accused Instrumentalities includes the wearable electrocardiography monitoring device of Claim 15, wherein the wireless transceiver is configured to communicate with an external device via Wi-Fi, mobile phone communication standards, or Bluetooth.*** The Zio Monitor satisfies Claim 26[a]. *See* 21[a].
26[b] wherein the electrocardiographic signals are converted to a different format, and	***The Accused Instrumentalities include the wearable electrocardiography monitoring device of Claim 15, wherein the electrocardiographic signals are converted to a different format.*** The Zio Monitor satisfies Claim 26[b]. *See* 21[b].
26[c] wherein the electrocardiographic signals are retrieved by one of a server, a client computer, and a mobile device via the wireless transceiver after the electrocardiographic signals are converted to the different format.	***The Accused Instrumentalities includes the wearable electrocardiography monitoring device of Claim 15, wherein the electrocardiographic signals are retrieved by one of a server, a client computer, and a mobile device via the wireless transceiver after the electrocardiographic signals are converted to the different format.*** The Zio Monitor satisfies Claim 26[c]. *See* 21[c].

Claim 27	**Accused Instrumentalities**
27[pre] The wearable electrocardiography monitoring device of Claim 15,	***The Accused Instrumentalities include the wearable electrocardiography monitoring device of Claim 15.*** The Zio Monitor satisfies Claim 27[pre]. *See* 21[pre].
27[a] wherein the wireless transceiver is configured to communicate with an external device via Wi-Fi, mobile phone communication standards, or Bluetooth,	***The Accused Instrumentalities includes the wearable electrocardiography monitoring device of Claim 15, wherein the wireless transceiver is configured to communicate with an external device via Wi-Fi, mobile phone communication standards, or Bluetooth.*** The Zio Monitor satisfies Claim 27[a]. *See* 21[a].
27[b] wherein the electrocardiographic signals are converted to a different format, and	***The Accused Instrumentalities include the wearable electrocardiography monitoring device of Claim 15, wherein the electrocardiographic signals are converted to a different format.*** The Zio Monitor satisfies Claim 27[b]. *See* 21[b].
27[c] wherein the adhesive covering the portion of the first face is provided on the first end section and the second end section only.	***The Accused Instrumentalities include the wearable electrocardiography monitoring device of Claim 15, wherein the adhesive covering the portion of the first face of the strip is provided on the first end section and the second end section only.*** The Zio Monitor satisfies Claim 27[c]. *See* 21[d].

Claim 28	**Accused Instrumentalities**
28[pre] The wearable electrocardiography monitoring device of Claim 15,	***The Accused Instrumentalities include the wearable electrocardiography monitoring device of Claim 15.*** The Zio Monitor satisfies Claim 28[pre]. *See* 21[pre].

Claim 28	**Accused Instrumentalities**
28[a] wherein the wireless transceiver is configured to communicate with an external device via Wi-Fi, mobile phone communication standards, or Bluetooth,	***The Accused Instrumentalities includes the wearable electrocardiography monitoring device of Claim 15, wherein the wireless transceiver is configured to communicate with an external device via Wi-Fi, mobile phone communication standards, or Bluetooth.*** The Zio Monitor satisfies Claim 28[a]. *See* 21[a].
28[b] wherein the electrocardiographic signals are converted to a different format, and	***The Accused Instrumentalities include the wearable electrocardiography monitoring device of Claim 15, wherein the electrocardiographic signals are converted to a different format.*** The Zio Monitor satisfies Claim 28[b]. *See* 21[b].
28[c] wherein the battery is vertically aligned with the wireless transceiver.	***The Accused Instrumentalities include the wearable electrocardiography monitoring device of Claim 15, wherein the battery is vertically aligned with the wireless transceiver.*** The Zio Monitor satisfies Claim 28[c]. *See* 21[e].

Claim 29	**Accused Instrumentalities**
29[pre] The wearable electrocardiography monitoring device of Claim 15,	***The Accused Instrumentalities include the wearable electrocardiography monitoring device of Claim 15.*** The Zio Monitor satisfies Claim 29[pre]. *See* 21[pre].
29[a] wherein the wireless transceiver is configured to communicate with an external device via Wi-Fi, mobile phone communication standards, or Bluetooth,	***The Accused Instrumentalities includes the wearable electrocardiography monitoring device of Claim 15, wherein the wireless transceiver is configured to communicate with an external device via Wi-Fi, mobile phone communication standards, or Bluetooth.*** The Zio Monitor satisfies Claim 29[a]. *See* 21[a].

Claim 29	**Accused Instrumentalities**
29[b] wherein the electrocardiographic signals are retrieved by one of a server, a client computer, and a mobile device via the wireless transceiver after the electrocardiographic signals are converted to a different format, and	***The Accused Instrumentalities includes the wearable electrocardiography monitoring device of Claim 15, wherein the electrocardiographic signals are retrieved by one of a server, a client computer, and a mobile device via the wireless transceiver after the electrocardiographic signals are converted to the different format.*** The Zio Monitor satisfies Claim 29[b]. *See* 21[c].
29[c] wherein the adhesive covering the portion of the first face is provided on the first end section and the second end section only.	***The Accused Instrumentalities include the wearable electrocardiography monitoring device of Claim 15, wherein the adhesive covering the portion of the first face of the strip is provided on the first end section and the second end section only.*** The Zio Monitor satisfies Claim 29[c]. *See* 21[d].

Claim 30	**Accused Instrumentalities**
30[pre]. The wearable electrocardiography monitoring device of Claim 15,	***The Accused Instrumentalities include the wearable electrocardiography monitoring device of Claim 15.*** The Zio Monitor satisfies Claim 30[pre]. *See* 21[pre].
30[a] wherein the wireless transceiver is configured to communicate with an external device via Wi-Fi, mobile phone communication standards, or Bluetooth,	***The Accused Instrumentalities includes the wearable electrocardiography monitoring device of Claim 15, wherein the wireless transceiver is configured to communicate with an external device via Wi-Fi, mobile phone communication standards, or Bluetooth.*** The Zio Monitor satisfies Claim 30[a]. *See* 21[a].

Claim 30	**Accused Instrumentalities**
30[b] wherein the electrocardiographic signals are retrieved by one of a server, a client computer, and a mobile device via the wireless transceiver after the electrocardiographic signals are converted to a different format, and	***The Accused Instrumentalities includes the wearable electrocardiography monitoring device of Claim 15, wherein the electrocardiographic signals are retrieved by one of a server, a client computer, and a mobile device via the wireless transceiver after the electrocardiographic signals are converted to the different format.*** The Zio Monitor satisfies Claim 30[b]. *See* 21[c].
30[c] wherein the battery is vertically aligned with the wireless transceiver.	***The Accused Instrumentalities include the wearable electrocardiography monitoring device of Claim 15, wherein the battery is vertically aligned with the wireless transceiver.*** The Zio Monitor satisfies Claim 30[c]. *See* 21[e].